DHEW HEALTH RESEARCH PRINCIPLES

Volume I

Documents Relating to the
Development of
Draft Health Research Principles
for the
Department of Health, Education, and Welfare

April - December 1978

Appendix C

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DHEW HEALTH RESEARCH PRINCIPLES

Volume I

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Development of
Draft Health Research Principles
for the
Department of Health, Education, and Welfare

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Appendix C

PUBLIC TESTIMONY ON THE DRAFT DHEW HEALTH RESEARCH PRINCIPLES

Prepared by the
Office of the Director, NIH

DHEW Publication Number (NIH) 79-1892

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
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The Living Bank
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American Brittle Bone Society
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INTRODUCTION

This Appendix contains copies of all public testimony considered in the development of the Report of the National Conference on Health Research Principles. These documents constitute the second major phase of public participation in the development of DHEW Health Research Principles.

In August, the professional societies and health organizations listed in Appendix A were recontacted and invited to participate in the National Conference. (A copy of the memorandum from the Director, NIH, which was sent to these groups is reproduced in Volume I). Individuals and organizations completing the Conference pre-registration form as well as others expressing interest in the Conference were sent the September 15 pre-Conference material which included the Draft DHEW Health Research Principles and other substantive documents to serve as a guide for the preparation of testimony. In addition, a notice was published in the Federal Register announcing the National Conference and inviting public comments.

Members of the public were provided a number of opportunities to present their views. Written testimony received by September 29 was referred to the appropriate Conference Panel and considered during the Panel's deliberations. Much of the first day of the Conference and a portion of the second day were devoted to oral testimony be pre-registered witnesses. In addition, written comments received up to two weeks after the Conference were referred to the appropriate Panel and considered in the development of the Panel reports.

This Appendix is organized by the five Panel areas which served as the substantive framework for the National Conference. (Individuals providing oral and written testimony were requested to designate the Panel to which their remarks were addressed.) Three categories of testimony are included within each Panel area: written testimony received before the Conference, in alphabetical order by organization; oral testimony delivered at the Conference, in order of witness appearance; and written testimony received after the Conference, in alphabetical order by organization. In order to have as complete a public record as possible, all written testimony received through December 1, 1978 is included in the latter category.

In addition to the five Panel areas, a final general testimony section is included which contains written testimony that was directed to two or more Panels as well as that for which a Panel was not designated.

PANEL 1

FUNDAMENTAL RESEARCH

massachusetts children's cancer blood program inc.
172 elm street, marlboro, massachusetts, 01752, tel. 617 485-7109

Testimony before the Panel on

Fundamental Research

National Conference on Health
Research and Principles

National Institutes of Health
Bethesda,Maryland

October 3,1978

by

Thomas J. Byrne
172 Elm Street
Marlborough,MA 01752

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PROJECT 76

GOOD DAY MR. CHAIRMAN; MEMBERS OF THE PANEL; OTHER DISTINGUISHED GUESTS AND VISITORS:

MY NAME IS THOMAS J. BYRNE OF MASSACHUSETTS, REPRESENTING THE MASSACHUSETTS CHILDRENS' CANCER BLOOD PROGRAM AND THE CITIZENS COMMITTEE FOR THE CONQUEST OF CANCER, DENVER COLORADO.

I AM THE FATHER OF A NINE-YEAR OLD SON WHO HAS HAD CANCER. HE IS ONE OF THE FEW WHO HAS SURVIVED, THANKS LARGELY IN PART TO THE ADVANCES IN CANCER TREATMENT. MY PERSONAL INVOLVEMENT PROMOTED ME TO LEARN AS MUCH ABOUT CANCER AS A LAYMAN CAN..... AND THIS LEARNING PROCESS, WHICH BEGAN WHEN MY SON MICHAEL WAS TWO YEARS OLD AND CONTINUES TODAY, HAS LED ME TO SEVERAL CONCLUSIONS....SOME OF WHICH I WOULD LIKE TO SHARE WITH YOU TODAY.

THE MOUNTING INCIDENCE OF CANCER, DOCUMENTED BEYOND QUESTION IN RECENT YEARS, PROMPTED THE EXPANSION OF THE COMPREHENSIVE CANCER CENTERS TO A TOTAL OF 18 BEGINNING IN 1972.

THIS EXPANSION PROVIDED THE BEST MEDICAL TALENT AND THE MOST COMPREHENSIVE TREATMENT AVAILABLE TO CANCER PATIENTS IN MANY SECTIONS OF OUR NATION. THE SAD TRUTH IS 18 IS NOT ENOUGH TODAY. PARENTS AGREE THAT AN IMMEDIATE INCREASE TO 23 WOULD BE DESIREABLE...AND I AM HERE TO ASK FOR THAT INCREASE.

BUT EVEN 23 CCCs, AS COMPREHENSIVE AS THEY ARE, WOULD NOT RELIEVE THE FINANCIAL AND PSYCHOLOGICAL BURDENS PLACED ON THE FAMILIES OF THOSE WITH CANCER. I MINIMIZE THE PROBLEMS WHEN I TELL YOU THAT, OUTSIDE THE NORTHEAST, IT IS NOT UNCOMMON FOR PARENTS TO TRAVEL UP TO 500 MILES...ONE WAY...TO HAVE THEIR CHILD TREATED AT A COMPREHENSIVE CENTER.

WE REALIZE TODAY THE STRAINS CANCER CAN INFLICT ON FAMILY MEMBERS; STRAINS THAT CAN...AND DO...AFFECT THE ATTITUDE OF THE PATIENT. AND WHO AMONG US DOES NOT REALIZE HOW IMPORTANT THE ATTITUDE OF THE PATIENT IS IN SURVIVING THE ONSLOUGHT OF CANCER AND ITS OFTEN-DEADLY SIDE-EFFECTS.

THE PARTIALLY SOLVE THIS PROBLEM, I AM SEEKING YOUR HELP IN A MOVE TO OPEN THE VETERANS ADMINISTRATION HOSPITALS THROUGHOUT THE NATION FOR OUTPATIENT TREATMENT OF CANCER PATIENTS...AFTER THEY HAVE BEEN DIAGNOSED AND THEIR PROTOCOL PRESCRIBED AT A COMPREHENSIVE CANCER CENTER.

THE COST-EFFECTIVENESS OF THIS IDEA ALONE COMMANDS ATTENTION. BUT THE PSYCHOLOGICAL IMPACT, THE SAVINGS IN TIME AND MONEY AND THE SPIRIT-LIFITING QUALITY IT CAN BRING TO PATIENTS AND THEIR FAMILIES OVERSHADOWS EVEN THIS IMPORTANT CONSIDERATION.

TOO OFTEN WE HEAR OF PATIENTS PASSING VETERANS HOSPITAL AFTER VETERANS HOSPITAL ON THEIR WAY TO A COMPREHENSIVE CANCER CENTER. AND WE DO NOT HEAR OF THE FAMILY WHO SETTLES FOR A COMMUNITY HOSPITAL ...EVEN FOR INITIAL DIAGNOSEMENT AND TREATMENT...BECAUSE THE NEAREST CENTER IS TOO FAR AWAY....OR TOO EXPENSIVE TO REACH.

IF WE HAD MORE CENTERS...IF WE OPENED THE VETERANS HOSPITALS TO OUTPATIENT TREATMENT, HOW MANY MORE PATIENTS WOULD RECEIVE THE FINEST TREATMENT AVAILABLE TODAY? HOW MANY MORE WOULD SURVIVE? HOW MANY MORE WOULD BE CURED?

ADMITTEDLY, THESE ARE TOUGH QUESTIONS. BUT THE CREATION OF MORE CENTERS, THE OPENING OF VA HOSPITALS AND THE OVERALL IMPROVEMENT IN TREATMENT THESE MOVES WOULD PROVIDE DEMAND A CLOSE AND CAREFUL LOOK.

THE END RESULT COULD BE MORE CURES....MORE LIVES SAVED. THE IMMEDIATE RESULT WOULD BE A DRAMATIC EASING OF THE BURDEN NOW CARRIED BY VICTIMS OF CANCER AND THEIR FAMILIES.

THANK YOU FOR YOUR KIND ATTENTION.

UNIVERSITY of PENNSYLVANIA

SCHOOL OF MEDICINE
PHILADELPHIA 19104

Hematology-Oncology Section
Department of Medicine

Hospital of the University of Pennsylvania
3400 Spruce Street
215-662- 3910

NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

October 3, 1978

Richard A. Cooper, M.D.

I represent the American Society for Clinical Investigation. We are a small organization with approximately 500 active members and another 1000 emeritus members. I am pleased to see that several of our members are on this panel. We are physician scientists trained to render care to our patients and committed to inquiry concerning the origins and treatment of disease.

Our research interests vary from fundamental biologic inquiry to clinical observation and applied research. Possibly because we participate in the interplay of these various approaches to disease we have an added appreciation for each.

The question facing this panel concerns the importance of one of these approaches: Fundamental Research. Where does it reside in the range of priorities facing the Department of Health, Education and Welfare?

If one defines applied research as the application of existing knowledge, then fundamental research is the creation of new knowledge. Is fundamental research important to the conquest of disease? I believe it is essential.

Breast cancer is a case in point. I care for many patients with this disease. Our best chemotherapy does not cure metastatic breast cancer - however, it adds comfort and prolongs the useful life of women, many of whom are in their most productive years. Among our best drugs is an anti-estrogen. The development of this drug would have been impossible without fundamental research in steroid chemistry and in endocrinology. Therapy with this drug is guided by the results of fundamental research concerning hormone receptors in cells. None of this research was carried out for purposes of developing an anti-estrogen drug; nor was most of this research even identified as cancer research. It was pure biologic inquiry. Was it important? For our patients it was very important.

Two points should be emphasized. First, it is impossible to know ahead of time how an area of fundamental inquiry will impact on disease. That was clearly the case for research leading to anti-estrogen therapy in breast cancer. Congress and the public must be educated to understand this.

Secondly, we should not expect that fundamental research will reduce the costs of health care. Although this may at times occur, more frequently health care costs will increase. I am impressed that above all the citizens of this nation want to lead lives free of the discomfort of disease and free of the threat of death in the blossom of life. From my experience as a physician, I believe that this desire transcends all material desires. Millions of dollars will be spent on anti-estrogen therapy in this country. Millions more were spent on the basic research which made the development of this drug possible. The comfort this drug will bring is immeasurable. I believe the citizens of this nation want us to develop basic biologic information which may permit us to devise ways to add comfort and years to their lives.

What does it mean to give a high priority to fundamental research? Let me further define what I mean by fundamental research. It is free, unincumbered biologic inquiry which has its origins in the creative imagination of the investigator. This research seeks its own support in the form of investigator-initiated grants. To the extent that funding is available for promising research proposals developed by investigators, I believe that fundamental research will prosper.

In recent years, three factors have decreased the availability of support for investigator-initiated research. First is a progressive rise in indirect cost rates. Indirect costs have become an important element in the fragile support systems for institutions involved in medical teaching and research. Stable systems of support for such institutions are essential. But this is a separate priority which overlaps only in part with the priority that must be given to research. I believe that the excessive use of research indirect costs for purposes of stabilizing medical school budgets is an ill-advised incursion into the pool of resources that should be available for the direct costs of research.

Second, in recent years there has been a diversion of research support away from investigator-initiated grants into special areas selected by agencies or by congress, the so called "diseases of the month." I am not certain whether the contracts and other mechanisms used to fund these special programs have always represented sound research investments - indeed, I believe that research resources have often been squandered. To the extent that the research budget is used in this way, less dollars are available for sound investigator-initiated research.

The third factor is the most recent: the growth of "technology transfer" as a part of the research mandate. The transfer of modern medical technology from medical centers to community hospitals should be a high priority. The need certainly exists. However, I believe it is ill advised to look to the NIH research budget to fund this activity.

The last subject I would like to address is the fundamental research scientist. We don't draft our scientists; they volunteer. Are we still getting the best? I am concerned about the steady decline in MD research investigators. We need stable training support and stable support during the critical early years of research experience so that young people can build careers in research; and good young researchers must see the promise of access to stable, investigator-initiated grant support.

In summary, I believe that fundamental research must have a high priority. The way to give it a high priority is by providing stability for research trainees in the form of training grants and fellowships, stability for young investigators in the form of career development awards and stability for creative scientists in the form of investigator-initiated research grants. This is the formula of the 60s that permitted an extraordinary degree of success. Somehow it gave way to the chaos of the 70s. As we look to the 80s, I believe we should return to these basic principles of research support with confidence that the creative mind is our greatest resource.

AMERICAN SOCIETY FOR PHARMACOLOGY
AND EXPERIMENTAL THERAPEUTICS, INC.

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HOUSTON BAKER
Executive Officer

1978 October 3

TESTIMONY

TO: NATIONAL CONFERENCE on HEALTH PRINCIPLES

FROM: Houston Baker, Ph.D. Houston Baker

SUBJECT: Fundamental Research

Basic research is the outstanding source on new knowledge. If we want to expand the rate of practical results, then likewise we must expand the base of knowledge from which they spring.

First, then, we must have dependable, continuing funding for basic research. I suggest that as a minimum, we should allocate a fixed fraction of our national resource for this purpose. For example, one percent of our Gross National Product would represent a modest commitment, especially when viewed in light of the research budgets of our most innovative, dominant corporations. Restoring stability to the commitment would additionally benefit us by reducing the counterproductive (and frightful) intensity of the grant application sweepstakes.

Mission oriented research has an important role to play, but it should not be permitted to swamp research initiated by investigators. A substantial part of our resources should be committed to outside researchers to assure collectively a broader perspective and wider base of knowledge applied to the search for knowledge.

Secondly, then, we need a substantial allocation to extramural research.

The history of science holds many examples of fundamental, even revolutionary, developments from unlikely sources - a patent clerk, tax collector, priest, printer-politician. Others have come from likely sources working on unlikely projects - the sort not usually funded now. Try, for example, a fishing expedition for unknown reaction products from a postulated metabolic pathway that led to the discovery of cyclic AMP.

Thirdly, then, we should devote a part of our resources to the unlikely, the esoteric, the candidates for the "golden fleece award" - which in its own day and way was quite a prize.

THE JOURNAL OF PHARMACOLOGY & EXPERIMENTAL THERAPEUTICS, PHARMAC AL REVIEWS, MOLECULAR PHARMACOLOGY, THE
PHARMACOLOGIST, RATIONAL DRUG THERAPY, CLINICAL PHARMACOLO APEUTICS, DRUG METABOLISM & DISPOSITION

Sue Thomas Hegyvary, Ph.D., R.N.
American Nurses' Association
Council of Nurse Researchers

Federal support for fundamental research has a remarkable but somewhat controversial history. While American scientists have attained many outstanding achievements in biological and behavioral sciences, a perpetual question has been whether federal funds should not be allocated more heavily toward care programs, with less expenditure for basic research. While health care programs built on current knowledge clearly need and deserve federal support, the American Nurses' Association, and I as its representative here, firmly support Secretary Califano's first principle: to maintain at a high level and to enhance our support for fundamental research into biology and behavior.

Our strong support of this principle may at first appear paradoxical. Nurses are users of knowledge from fundamental research both biological and behavioral, in the care of patients and in investigation of clinical problems. We have urged that greater attention and support be directed toward the development and study of preventive and rehabilitative programs. At the same time, however, an increasing cadre of doctorally prepared nurses are engaging in fundamental research. As we have learned to look more closely at the clinical setting and the problems presented by patients and family, we also have learned to put those problems and questions into the realm of scientific investigation. In some instances, clinical investigation is appropriate; in others, research in the sciencesbasic to clinical practice is necessary.

Perhaps some examples of nursing research projects now in progress will help to illustrate the nurses' concern for support of both fundamental and clinical research. On the basis of her clinical practice with cardiac patients and subsequent study of physiology, Dr. Sue Donaldson at Rush University is studying ontogenetic differentiation of striated muscle types, particularly cardiac muscle, and the development of the depressant effect of acidosis on muscle. She has noted that embryo muscle is not sensitive but the sensitivity develops later. In looking at clinical problems, such as preventing or dealing more effectively with cardiac ischemia, she is questioning when cardiac muscle becomes sensitive, whether sensitivity changes with pressure load, and what parameters determine the changes as part of growth and development.

Dr. Anderson-Shanklin at the University of Florida has conducted extensive study of the sucking response in infants. After considerable basic research, her findings could be used to determine the readiness of the infant for oral feedings.

Dr. Jean Johnson has conducted extensive studies of the pre and post-operative patient in testing theories about human behavior and adaptation in this stressful situation. Her clinical studies of behavioral responses in the surgical setting have proved very useful in clinical practice, and also have provided a foundation for investigation of behavioral, physiological and environmental variables in the postoperative setting.

My own federally funded studies of the quality of nursing care have built on the work of many fundamental and applied researchers in both biological and behavioral disciplines. In addition, our field research has raised many questions that must be referred back to basic science research for further study, for example, the relationship between ambulation of postsurgical patients and the maintenance of normal blood pressure, the inverse relationship of some measures of anxiety in cardiac patients as compared with other groups studied, and the effects of the social environment on patient recovery.

These and many other possible examples of nursing research illustrate the essential interaction between fundamental and clinical research, as well as the need for simultaneous investigation of biological and behavioral variables. We believe that health research should have present or potential clinical relevance. We also believe, however, as Comroe points out in his book The Retrospectroscope, that the importance of discoveries is difficult, often impossible, to assess at the time discoveries are made. Perhaps an appropriate example of clinical applicability and the need for the scope of biological, behavioral, social, and epidemiological research is the case of Menkes disease, the so-called "kinky hair syndrome" in newborns. Infants with this condition were first noted to be frail and to have kinky hair. Further observation revealed that they also had mental retardation, severe anemia, neutropenia, and were blind. It is now known that the condition is based on deficiencies of zinc and proteins necessary for zinc transport. But this clinical discovery was not made simply by measuring the infant's zinc levels. Someone learned that kinky hair syndrome also exists in sheep. A survey of Australian sheep growers produced the finding that sheep indeed do have kinky hair syndrome, but only if they graze in an area with a low zinc level in the soil. The results of these studies is now obvious in the treatment of this disease. But how would one have applied the criterion of direct clinical applicability to the extensive prior studies of zinc binding and transport or of body proteins and enzymes?

The question of cost-effectiveness similarly is raised in regard to fundamental research. We submit that cost-effectiveness in the present tense is and will remain an unknown quantity in fundamental research (except in the very simplistic view of precisely the same design and "all other things equal" for differing dollar amounts). The effectiveness of fundamental research is very long-range, for example, the binding and transport of zinc.

In summary, the American Nurses' Association supports the principle of continued and improved support for fundamental research in behavior and biology. As clinicians, we value and need the solid foundation upon which the house of clinical practice is built, both for the present and future generations.

DR. HOWARD E. MORGAN

TESTIMONY FOR THE AMERICAN HEART ASSOCIATION

At a Conference Convened by the Department
of Health, Education and Welfare Secretary Califano October 3 and 4, 1978

Panel I, Fundamental Research

This testimony is submitted on behalf of the American Heart Association. The Heart Association is a voluntary health agency whose mission has been to reduce death and disability from heart disease through the course of its thirty years of existence. During that course it has continuously recognized the importance of fundamental research in meeting its mission goal. During the current year the total investment of the American Heart Association in research will amount to something in excess of $21 million.

It should be emphasized that the Association supports broad areas of fundamental research, not just investigation of the structure and function of the cardiovascular system. The focus continuously has been on the quality of science represented in the projects.

The Association has three principles to suggest to the Panel on Planning for Fundamental Research. Principle #1 is that it is essential to reinforce the commitment of federal agencies to support of fundamental biomedical research. It is not appropriate to accept the postulate that because the investment is large it has reached some theoretical limit. The only appropriate limit on expenses for basic biomedical research should be the availability of proposals for scientific study which are meritorious enough to promise benefit to the health of the American people. The Association believes strongly that substantial advances in the recent past have derived from good science aimed at answering fundamental biological questions. The Heart Association takes exception to a statement contained on page 7 of the draft document from the Department of Health, Education and Welfare.

This statement suggests that "basic research is surrounded by and must relate closely to an area of applications research." In the opinion of the Association, this is clearly a confusion of priorities that is not useful to the cause of fundamental research. By definition, basic research is undertaken at the level of the limits of current knowledge and cannot be made to rest on any constraint of relevance.

In context of this principle, monies devoted to fundamental research, must be strongly oriented toward investigator-initiated proposals. In determining priorities for support of these proposals, the peer review system has continued to prove its worth. Because of financial constraints, there currently is a threat to the peer review process arising out of excessive workloads which preclude careful and dispassionate evaluation of scientific merit. This trend should be reversed.

Secondly, provision must be made for the training of the next generation of research scientists. The drastic curtailment of training programs is now beginning to be seen as a net defect in our ability to maintain research momentum.

A pressing consideration in the replacement of our skilled scientist population is training of physicians with research capacity to allow them to enter careers in science. There is convergence of information from both the laboratory and bedside that this population of scientists are in a unique position to use in advancing both fundamental knowledge and its application to health problems.

Third, provision must be made in the planning process to upgrade and refurbish research plant facilities that have been permitted to become outmoded.

The second principle suggested by the Association is that any proposal for targeted research support be assessed by informed scientists familiar with the status of research in the area, the scientific opportunities available, and the scientific merit of the proposal. These criteria are well-recognized in their application to fundamental research, but they need to be expanded to areas now being spoken of as unmet needs. These needs are variously characterized as health care research, large scale epidemiological trials, and research leading to assessment of therapeutic efficiency. The Association clearly recognizes that some of these areas do require attention, but assessment of the worth and priority of such projects must begin with an impartial evaluation of scientific soundness.

As the final principle, the American Heart Association proposes ~~is~~ that funding of new research missions be phased in only in relation to the availability of new monies. In that way funding of new research missions will not subtract from the stable support of ongoing productive research. Evaluations for scientific merit of new projects should be carried out side-by-side with existing programs. Unless a clear case can be made that the merit of the new proposal is so high and the need so urgent as to displace existing programs, their initiation should depend on availability of new funds. The orderly progression of scientific investigation requires stability for the investigator to pursue his studies for a reasonable interval of time without interruption. On the other hand, he must subject himself to evaluation by his peers every few years. This review clearly implies that the non-productive investigator will not be authorized to continue his studies.

The greatest service which can be done to promote biomedical research is to re-establish the principle that support of fundamental research is a primary health research mission of this country.

Thank you very much for the opportunity to testify in these deliberations.

Remarks by Professor Richard B. Middleton, College of Medicine and Dentistry of New Jersey-New Jersey School of Osteopathic Medicine, P.O. Box 55, Piscataway, New Jersey 08854 before Panel on Fundamental Research, National Conference on Health Research Principles, October 3-4, 1978, National Institutes of Health, Bethesda, Maryland.

Dr. Seldin and members of the panel on fundamental research. I am pleased to have this opportunity to add my remarks to those of the large number of interested persons who are making statements before this panel. I am a professor in the third and newest medical school in New Jersey and have been involved in basic research for more than 20 years. The American Association of Colleges of Osteopathic Medicine asked me to speak to you.

I would like to speak on three aspects for the consideration of this panel. These are the essential value of fundamental research to our society, the role of academic institutions in fundamental research, and the need for continued federal support for fundamental research.

1. Scientists who engage in fundamental research seek knowledge and hope to gain understanding of the natural world. I believe that the most creative members of our society are likely to be found amongst persons who are encouraged to undertake fundamental research. There can be little doubt that the most creative research is investigator initiated. Various studies over the past 15 years have concluded that in recent decades the greatest advances in science have taken place in this country which has, since the Second World War, strongly promoted investigator-initiated research.

2. I believe that society expects academic institutions to undertake fundamental research. This attitude is reflected in the generally strong support of universities by individuals, foundations and governments. Universities and medical schools have an academic tradition of intellectual curiosity and intense research activity. Scientists in universities are encouraged to assess the state of background knowledge and available techniques in their areas of interest and to propose investigations which will make use of their skills and those of potential collaborators.

This tradition lends itself to investigator-initiated research and to continued assessment of the quality (a) of the research process and (b) of interpretation of the results. Members of the academic community have developed and make customary use of peer review to evaluate the accomplishments of their colleagues.

In some respects medical schools are particularly well suited for certain areas of fundamental research within the biomedical sciences. The interactions amongst the various groups in a medical school environment may lead to synergistic promotion of fundamental research and a shortening of the lag between confirmed research results and innovative approaches to therapy and health care. Several new medical schools have opened in recent years. They are staffed by highly motivated and well trained scientists who are well equipped to propose and undertake fundamental research.

3. For the foreseeable future adequate research funds of the necessary scale must be provided by society through the federal government. These funds must be stable and predictable over the long term and grow sufficiently to result in the continued yield of more knowledge and greater understanding of natural processes. Attenuation of funding for fundamental research will lead to the lack of new basic knowledge which is essential for the development of technology based on scientific activity. If funds are made available for fundamental research, we can be certain that interesting results will be produced. The alternative seems equally clear. If funds are not made available for fundamental research, we can be certain that no interesting results will be produced.

On behalf of scientists who are engaged in fundamental research, I wish to thank the panel for their willingness to participate in the preparation of a timely and, I trust, influential report on the need for continued federal funding for fundamental research in the United States.

FOCUS 1: FUNDAMENTAL RESEARCH

Presented at the National Conference
on Health Research Principles

October 3-4, 1978

National Institutes of Health
Bethesda, Maryland

Presented by Presented by Jerry M. Neal, Ed.D.

for

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and

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INTRODUCTION

The Society of Teachers of Family Medicine is comprised on approximately 1,440 members, all involved in family medicine education and training programs. It is an interdisciplinary society with members representing medicine, social work, education, pharmacy, administration, nursing, the behavioral and social sciences, and other fields. Our members pursue their professional activities in medical schools, community hospital teaching programs, and in a great variety of community-based teaching practices. In the spring of 1978 the Research Committee of the Society was charged to review and articulate principles and strategies which might profitably govern the research efforts of those in our discipline. That work began during the past summer and was accelerated in response to Secretary Califano's request for input into the development of a federal strategy for supporting health research. The document presented here has been prepared by a task force of the Society and will be submitted to the organization's board of directors at its next meeting in October, 1978. Many of the members who are involved in research also participate in the North American Primary Care Research Group. This testimony is a joint effort of these two organizations.

FOCUS 1: FUNDAMENTAL RESEARCH

While all levels of the health research continuum contribute to advancements in health care services, promotion and prediction, basic research provides the critical foundation on which the other levels build. For this reason, we believe a national commitment to fundamental research is essential and that the principles guiding federal funding for fundamental research are most important as they eventually impact on all other levels of health research.

A DHEW program for funding fundamental health research should be comprehensive. It should support alternative research approaches; a broad range of research areas (including behavioral, social, and environmental sciences as well as the biological); and futuristic research.

- Alternative research approaches -- Many investigative techniques have been developed by the disciplines of sociology, agriculture, economics, epidemiology, public health, health care administration, and others which are appropriate for research issues of health disease and health care delivery. Projects which blend the advantages offered by these disciplines should be encouraged. Such integration could occur, for example, through a broadly trained researcher or use of an interdisciplinary research team.

- A broad range of research areas -- The health of an individual or community is greatly effected by extrinsic factors as well as intrinsic ones such as researched by the physiologist or biologist. Indeed, such factors as pollution, nutrition and life style may affect health more than biological factors. Thus, basic behavioral, social and environmental investigations as they relate to health should be supported.

- Futuristic research as well as foreseeably applicable research areas -- It is easiest to speak for the support of basic research that, given a few more years of fundamental research, will likely yield an applicable result. Futuristic research, however, should also be solidly supported. While futuristic areas of research do not have clear ties to applied fields, they can demonstrate great promise through theoretical rationales. A past example of such research is B.F. Skinner's early research with rat behavior, that then enjoyed only a theoretical link to human behavior. That theoretical link has materialized into meaningful programs in retardation, mental health, smoking, and weight control, to name only a few.

A DHEW program for funding fundamental research should be consistent. It should be long-term, stable, responsive, and self-correcting.

- Long-term -- the knowledge base of many health related areas can only be strengthened and extended through long range studies. Research in areas such as the family life cycle and the individual life cycle require longitudinal designs. Early indications are that by the modification of the life systems we can reduce health risks for artheriosclerotic heart diseases, cancer, automobile accidents, alcoholism, etc. A firm long-term commitment is necessary to affirm these early indications and to assure a research base for such areas.

- Stable -- A federal program must be stable as well as long-term. Since many research studies require major investments of money, building construction and careers, a stable level of commitment is necessary to allow researchers or research centers to pursue a research project to fruition.

- Responsive -- Each year, new areas of potentially productive research emerges. Thus, a five year blueprint for research funding must plan for the unexpected and reserve funds for new proposals that will not be submitted until year 4 or 5.

- Self-correcting -- The necessary program characteristics, long-term and stable, must be balanced with the important ability of the funding agency to cease support on non-productive projects. The criteria for halting support to a project should be stated early, mutually understood, and non-political.

In summary, a DHEW program for funding fundamental health research should:

1) be comprehensive, that is, support: alternative research approaches, a broad range of research areas (including behavioral, social, and environmental sciences as well as the biological), and futuristic research.

2) be consistent, that is, long-term, stable, responsive, and self-correcting.

TESTIMONY

Lowell M. Greenbaum Ph.D.
Professor of Pharmacology
Columbia University

Representing

Public Affairs Committees:
Federation of American Societies
for Experimental Biology
American Society for Pharmacology &
Experimental Therapeutics

Before

PANEL ON FUNDAMENTAL RESEARCH

October 4, 1978

I welcome this opportunity to participate in the development of health research principles and I speak on behalf of two bodies who have devoted an extraordinary amount of time in the areas of public affairs and science and government and science.

We certainly endorse the major principle concerning fundamental research as stated in the memorandum, that is, " A national commitment to fundamental research is essential to meet the full range of public health expectations." We support in particular this concept as it applies to basic research. Basic biomedical research is the long range answer to disease control and prevention. It is generally agreed that the cost/effectiveness of basic research is very impressive if not outstanding. However, there are many who would generally agree that support of basic biomedical research in this country has been waning and consequently may be in some difficulty. The memorandum itself contains several "themes" (attachment #3, pg. 1 & 2) which clearly indicate concern over future commitments to basic research.

One of the themes states: "There is need for a renewed national commitment to basic biomedical and behavioral research". We would comment that such a commitment in funding is essential to continue established important research programs, to promote new areas of research and to generate enthusiasm of younger minds to pursue a career of biomedical research. Despite good intentions by government officials, many of my colleagues and myself, are not convinced that we have such a commitment at this time. I can cite the most recent budget of the President as evidence for this. The budget for fiscal 1979 for the National Institutes of Health contained two specific major items in terms of support for biomedical research. One was the the appropriation of 94 million dollars earmarked specifically for basic research, the second was the return to the budget of of the Biomedical Research Support Program. Unfortunately, despite these commitments,the total budget was such that if Congress hadn't intervened the budget would have permitted less than 30% of approved competing research grants from being funded. This would be 12% less than the year before and would mean the loss of of 1530 competing regular research grants. Fortunately Congress intervened. The need for future commitment is obvious.

Another theme which deserves comment is that " there must be diversity in the research supported. Greater recognition should be given to research in the behavioral, social and population sciences epidemiology and biostatistics. There follows some 37 disciplines and diseases which are listed as meriting additional emphasis.

Our comment to this is that favoring support of research in many if not all disciplines and diseases is fine if there is a dollar commitment to go with it. The list of disciplines that support is suggested for is painfully large especially since there has been little growth of our biomedical budget in real dollars in many years. If we are not to get a dollar commitment in terms of current research budgets, if we have no funds to refurbish our laboratory equipment than how are we going to do this. We must not to overexpand our research goals, especially since we are currently stumbling along financially trying to reach our current goals. The successes we now enjoy should not be blunted by having to compete for the dollar with "the disease of the month", by forced application to clinical research or targeted research.

The final comment that I will make is that I was very suprised to see in the memorandum (Attachment 2, page 7) the "sub-principle" that "basic research is surrounded by and must relate closely to an area of application research." If this statement means that all basic research must end with an application and that all doing basic research have some commitment to applied research, then we haven't learned a thing about basic research and its meaning. If on the other hand, the statement means that basic researchers have some cognizance of what their findings could mean in applied manner than I think the "sub-principle" should state this clearly.

To summarize our comments:

We agree that a renewed national commitment be made to basic research but we are convinced that without a dollar commitment, this will be not be very effective.

We urge caution in setting expanded research goals because we see a limited number of dollars for research.

We reject the concept that basic research need result in applied research although we believe that the strenghth of future breakthroughs in disease prevention and control lies in the support of basic research.

Thank you for this opportunity to comment.

Problems Facing Fundamental Research

National Conference on Health Research Principles

October 3, 1978

Lester A. Mitscher, PhD
Kansas University Distinguished Professor and Chairman
Department of Medicinal Chemistry
Kansas University, Lawrence, Kansas, 66045

In the years following the Second World War, biomedical research flourished in The United States. Many practical and fundamental discoveries were made; scientists from many foreign countries came here to gain increased expertise; the economic value of the drugs produced contributed heavily to our favorable image at home and abroad, to our balance of payments, and to the health and welfare of our citizens. Pharmaceutical scientists, including those from the academic community I represent, are proud of the role they played in this. Contrary to what one might expect, The United States is not particularly resource rich in the basic materials needed to support this activity. Synthetic drugs are mostly based upon petrochemicals; major drugs of natural origin (such as opium, quinine, diosgenin -- needed as a raw material for the "pill" --, etc.) are based upon vegetative plants which largely grow elsewhere in the world, and fermentation (needed for the production of antibiotics) is a labor intensive activity going more and more overseas. Our commanding postwar lead in these areas was not, then, based as much upon abundant raw materials as upon our organizational ability in setting up complex, directed screening programs and translating basic discoveries into clinical realities, the availability of suitable numbers of highly trained professionals, a highly developed system of free inquiry in which quality ideas could be investigated rapidly, the availability of sophisticated equipment, the venture capital to make it all work, and the mutual confidence that kept everyone's enthusiasm high. I wish I could say that these factors still characterize biomedical research in The United States, but I cannot.

The reasons underlying our deteriorating position are many but I believe can be traced to two fundamental factors whose correction would lead to an amelioration of many of the factors which cascade from them. These two factors are:

1). Lack of a continuous pool of financial resources of sufficient magnitude to provide continuity of effort simultaneously in applied and fundamental research.

2). Vastly multiplying new regulations and reportage requirements which absorb the time, energy and creativity of an important percentage of the biomedical research community and alter the demand for new personnel away from basic research to increasingly data gathering and defensive roles.

The diseases which remain to be conquered (cancer, cardiovascular disease, stroke, etc.) are complex with basic causes as yet only dimly perceived. Successful attack must involve advances on a broad front, often by teams of specialists, and this cannot be done by overnight crash programs that drain resources from other areas of potential value. Nor can we afford to change national priorities suddenly and drastically. It takes time and resources to build up successful programs of research and these should not be dispersed on short notice for reasons other than lack of scientific merit. Nor should individual investigators languish for lack of funds. There are many spokesmen here for basic research and I endorse their views. I also represent a special constituency of scientists whose instincts and preferences are in application of basic discoveries to new and improved therapy. Applied pharmacology, drug design and synthesis not involving unusual reactions, biopharmaceutics, the study of dosage forms, and many newer, less traditional, areas of inquiry are not faring well given the current intense competition for the relatively small amount of new money available each year for research. Do not misunderstand. We are glad to have any funds at all available for competition and we are well aware that peer review is one of the strongest possible and fairest methods of ensuring high-quality research for the taxpayer's dollar, but distinguished scientists with priority scores below 200 are now going unfunded and many meritorious proposals, particularly from smaller schools, in specialties without broad public visibility, and younger investigators are having funding problems. This and the ruinous rise of the cost of materials for doing research present us with a funding crisis of considerable magnitude from which the investigators at the smaller schools typified by most pharmaceutical investigators suffer disproportionately. There are no external alternate funds for many to turn to. The drug industry has only very modest budgets for external support of non-clinical research. The states provide laboratories and professional salaries but only very modest operating funds. Many of us have spent a whole generation to bring pharmaceutical research in the universities to a level comparable with the best available elsewhere. It is hard for us to see this struggle escalate in difficulty while so many are still struggling against the disadvantages of heavy teaching loads, poor facilities, small faculties and indifferent administrations.

The escallation of regulations on the conduct of research and the application of its fruits and the concomitant blizzard of forms to be filled out and filed at every level of administration (department, college, university, municipal, regents, legislature, NIH, NSF, OSHA, animal care, AEC, affirmative action, etc.) without provision of funds or manpower to do this work means that many of us are spending more and more time away from our primary functions. We should spend a majority of our time in innovative pursuits; lecturing, in the laboratory, in the library, at technical socieities, etc. The increased time we spend non-creatively in adversary relationships with administrators, accountants, etc., takes time, energy and creativity away from the innovation for which we are trained and for which our positions were created. At a time when fewer are electing careers in science, the pool of active scientists is effectively diminished further by these demands on our time. This is one of the causative factors for the lessening of our productivity compared to other nations and the impact of this is still not fully felt. The rigidity regulations impressed on research by its nature inhibits innovation.

Provide more research funds and turn down the spigot from whence all but the most essential paperwork flows, and the things which are wrong with our research capabilities will begin to right themselves and this country will once again lead the world in biomedical research with its attendant humanitarian and economic benefits. Ancillary problems such as the decreasing percentage of our youth willing to invest 15 years of hard work for a career in science, the flight of research support capital overseas, aging and deteriorating equipment, student support at the poverty level, the shake out between have and have not schools, the drug lag, and so many others will subside to more manageable proportions.

Specific practical proposals for accomplishing these goals should be top priority for this conference. I have several such suggestions and will share them on request and will bring them up during the working panel deliberations.

Lester A. Mitscher

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Presented by
ROBERT P. LOWMAN, Ph.D.
Scientific Affairs Officer

I am pleased to have this opportunity to address the Panel on Fundamental Research and to present some views which are representative of those held by members of the American Psychological Association.

There are three major points I wish to make today about the proposed Health Research Principles. First is the importance of recognizing that health research includes research in the behavioral and social sciences. Second is the importance of stressing prevention, or health, rather than cure, treatment, or disease. Third is the relation between basic and applied research, and my feeling that the former need not be justified by the latter. I will speak briefly on each of these points.

One of the Health Research Principles reads: "This [research] base should include studies in the behavioral sciences . . . ." On the surface, the language I have just read indicates that DHEW is sensitive to the importance of the behavioral sciences in health research. The facts do not support this conclusion. About 11% of the doctoral level scientists in the U.S. are psychologists, yet these psychologists receive only about 1.5% of the federal funds for basic research. These data speak eloquently about the importance DHEW has attached to basic research in the behavioral sciences.

Related to this point, there seems to be a tendency to equate "basic" research with "molecular" research and to assume that research conducted by most behavioral and social scientists is, by its very nature, applied. I do not believe this is the case. There is basic research in every field worthy of support, and DHEW must recognize that basic research into social processes related to health is of quite a different character than basic research into cell biochemistry. Both kinds of research are important, and both should be vigorously supported.

Prevention is the theme of my second major point. Prevention occurs only twice in the proposed Health Research Principles on Fundamental Research. I feel this is an inadequate emphasis. The prevention of disease, or the maintenance of health, is a far more important topic that DHEW research expenditures would suggest. In terms of extending life, the payoff from research on prevention far exceeds that of research on treatment or cure, and it should receive an emphasis indicative of that fact.

It is important to point out that prevention deeply involves the behavioral sciences, and that prevention research in the behavioral sciences cannot be completely tied to a disease model. While it was possible to develop a vaccine for polio, there will be no vaccine for phobias. Similarly, the behaviors which may reduce the incidence of heart disease are probably applicable to the prevention of other disorders as well. I am concerned that, particularly within NIH, the institutional structure is almost completely disease oriented, to the possible detriment of research on prevention.

Finally, two of the principles speak to the relation of basic to applied research. I am particularly concerned with the principle that reads "Basic research must relate closely to an area of applications research." I believe this is not a wise principle to adopt. We cannot predict very well which basic research will result in an important application, and we should not try to.

What we should do is support the best basic research we can in all fields. If we do this, applications will follow.

Now I am not saying that basic research should never be targeted. Clearly, applied research depends on a knowledge of certain basic principles, and if these are not known, applied research cannot go forward. What I am saying is that most basic research should not be targeted, and that targeted basic research should be used sparingly, and only when there is a clear reason to do so.

In summary, there is much to support in the proposed Health Research Principles on Fundamental Research. Certainly, stable levels of support are important. Investigator-initiated research is very important, and a reasonable level of federal support for fundamental research is a sound investment in the future. However, I would like to leave you with three thoughts. Support for research in psychology and the behavioral sciences generally must be a fundamental commitment of DHEW, and levels of support must reflect that commitment; prevention is preferable to treatment, and research on prevention should play a more important role in these research principles; and while basic and applied research are both important, the former should not be justified by the latter.

Thank you for the opportunity to present these remarks.

10/3/78

STATEMENT ON FUNDAMENTAL RESEARCH

Thomas Roth, Ph.D.

Chief Officer, Association for the Psychophysiological Study of Sleep
Retiring Executive Secretary-Treasurer, Association of Sleep Disorders Centers
Director, Sleep Disorders and Research Center, Henry Ford Hospital, Detroit, MI

On behalf of the researchers and clinicians of the Association for the Psychophysiological Study of Sleep and the Association of Sleep Disorders Centers, I wish to thank the Committee for this opportunity to present our views on the important topic under consideration at this conference. I intend to accept as self evident the need for fundamental research and its important role in improving public health and supporting other Department health missions. My comments will be focused on three general themes: the definition of fundamental research, aspects of fundamental research that pose particular problems for new disciplines, and the principles that should guide federal funding of fundamental research. My views are derived from the experiences I and my colleagues have had with sleep research. This area of research serves as an instructive model for several reasons: it is a relatively new field of research, it is inherently inderdisciplinary, and it is expensive to conduct and is therefore especially dependent on federal support.

I view fundamental research as any research which is conducted primarily to increase understanding of the mechanisms of the phenomenon in question. Conversely, applied research is any research in which the primary goal is to assess the efficacy or usefulness of a procedure or manipulation. Under my definition, there are two types of fundamental research -- phenomenological research and manipulative research. Although experimental manipulation is a hallmark of science, at least some phenomenological or descriptive research must precede any enlightened manipulative research. In some fields of science, such as astronomy, descriptive research comprises the preponderance of the research. To be noted is the rejection of the principle that fundamental research is exclusively animal research.

For much of medical history, it has been the belief that sleep problems and associated problems of wakefulness are relatively benign, if vexing, complaints, and that people rarely die of sleep disturbance. Today we have a more cautious view. A few statistics will make my point. An American Cancer Society survey suggested that mortality rates are increased for persons who report obtaining less or more than seven or eight hours of sleep each night. One sleep complaint, insomnia, chronically afflicts up to 10% of adult Americans; another, narcolepsy, is suffered by more than a quarter million citizens. In 1976, there were over 30 million retail drugstore prescriptions for sleeping pills, or one for every seventh American. It has been estimated that the total annual cost of dispensing sleeping pills in this country is $490 million; this figure does not include the unknown amounts spent on non-pharmacological treatment of insomnia or on treatment of any of the numerous other sleep disorders. Finally, it is now clear that physiological function, and especially respiratory function, follows different laws in the sleep and awake states, and that one must examine both states when searching for abnormal signs in patients and when evaluating the effects of therapies.

Techniques for basic research on sleep were not fully developed until the early 1950's, and we are only now beginning to understand the phenomenology and mechanisms of normal sleep. Because understanding of the abnormal presupposes knowledge about the normal, we presently have very little information on the phenomenology and mechanisms of complaints and disorders associated with sleep.

Perhaps the frustration that burdens sleep researchers most, and the one that most dampens their natural enthusiasm for their work, results from the lack of a true home within the research funding community. Both the newness of the field and its inherent inderdisciplinary nature contribute to this situation. There are no mechanisms for systematically identifying and incorporating into existing funding systems worthy new research areas. Further, although most would support the assertion that interdisciplinary research is necessary, in practice proposals for such research get shunted from one agency to another, without any apparent concern for the merit of the interdisciplinary endeavor.

So, the first obstacle for a researcher in a new and interdisciplinary field is to find an agency which will even consider his or her research proposal. The next is the virtual certainty that genuine peer review will not take place. If a field is not yet recognized, it is unlikely that funding agencies will have identified experts in the field and will have asked them to participate in the review process.

Other obstacles that sleep researchers must face derive from the fact that their research is expensive to conduct. The expense is primarily the result of the lengthy periods of observation required in both animal and human studies and the special training required of personnel. To be new and expensive is a double burden when federal support is sought, but the expense involved almost dictates that the federal government be the primary support resource. Further, the expense contributes much to discouraging young investigators from entering the field: only the very courageous have the stamina to combat the resistance to supporting a young investigator in a new field that is quite expensive.

If sleep research is representative of other fields that have come of age in recent years, when the emphasis has been heavily tilted toward applied research, there is an imbalance among various parts of the research continuum. An example will illustrate my point. I recently conducted a Medline bibliographic search on the topic insomnia; over 75% of the articles were drug or other treatment-oriented studies, 15% were review articles, and only 10% were systematic studies of the nature of insomnia. These figures become impressive when it is realized that we can presently identify the etiology of insomnia, or at least make a presumptive diagnosis, for at most 40% of patients. We therefore know far more about the treatment of insomnia than about what it is we are treating. Further, to be noted is that most of the treatment-related research was supported by pharmaceutical companies who had a vested interest in excluding consideration of non-pharmacological modes of treatment. This bias is understandable, but must be weighed against the fact that sedative-hypnotic drugs offer only symptomatic relief of insomnia, that they are appropriate for only certain types of insomniacs, and that they contribute significantly to the current drug abuse problem in this country.

My final remarks concern the principles that should guide decisions about which research areas, new or old, should receive support. The decisions should be based on answers to three questions: Is the research related directly or indirectly to a major health problem in this country? It is likely that the research will produce useful advances in basic knowledge or in clinical knowledge? Is it likely that researchers currently active in the field will realize the potential inherent in their field? Only areas for which the answers to all three questions are "yes" should receive heavy research support. Obviously, there should be a periodic re-assessment of the answers, and levels of support should reflect any changes in the answers.

In conclusion, I believe that fundamental research as I have defined it must receive continued and increased federal support. We must devise methods for assuring especially that research in new and interdisciplinary fields does not get lost in the funding system. And funding decisions for fundamental research should be guided by the principles of clinical relevance and the likelihood of payoff both for the area and by its researchers.

Fundamental Research

Dr. G. R. Noggle, Ph.D.
American Society of Plant Physiologists
9650 Rockville Pike
Bethesda, Maryland 20014

The Department of Health, Education, and Welfare through the National Institutes of Health has not been a major supporter of plant physiological research. The usual response to plant scientists submitting grant requests to NIH is that there are more appropriate agencies (USDA,EPA,DOE) in the business of supporting basic plant science research. There are, however, some exceptions and NIH has provided long-term research support to a number of plant physiologists. A major feature of this support has been the commitment of funds for a number of years rather than in yearly increments. The long-term support provides continuity to the research effort and allows for the best use of personnel and facilities. This feature of research support should be expanded in future NIH research grants.

Recently a new problem of biomedical concern has developed because of the widespread use of potentially harmful chemicals in industry and agriculture. It is the agricultural problem that I wish to expand on since it illustrates the need for a long-term cooperative research effort between plant physiologists and biomedical scientists. The relationship of this problem to human health has been documented but no major research effort has been initiated.

Many different kinds of chemicals are applied to plants to control insects, fungi, bacteria, nematodes, and weeds; to alter plant form or growth habit; to modify metabolic pathways; or to change their chemical composition. As modern agriculture responds to the need for increasing production of food, fiber, and fuel, the use of chemicals will increase. For some purposes it is sufficient that the chemical be applied to the outer surface of the plant to protect against insects, fungi and bacteria. In other instances the applied chemical must be absorbed through leaf or root surfaces and then transported within the plant before biological activity is achieved.

The relation between chemicals used on plants and animal or human health has not gone unnoticed. Many fungicides, bacteriocides, and insecticides are known to have harmful effects on man or other organisms and their uses have been restricted or prohibited. These chemicals usually are applied to external plant surfaces and their effects are expressed at the plant surface. The deleterious effects of such chemicals on man can be minimized by appropriate application techniques and pre- or post-harvest treatments. The possible human health hazards of such chemicals remains a concern of the manufacturers, the Environmental Protection Agency, and to a lesser degree, the US Department of Agriculture.

Chemicals applied to plants for weed control, for the alteration of metabolic pathways, or the modification of form or growth habit must enter the plant before an effect is expressed. The chemical is absorbed through root or leaf surfaces and then is transported within the plant to a sensitive target site where some biochemical event is triggered. The chemical at the target site generally is not the same chemical applied to the plant. During absorption and translocation the chemical is in contact with biochemically active cells which alter its structure and biological activity .

When it is recognized that dozens of chemicals are routinely applied to plants, the numbers and kinds of compounds which may be present in plants assumes some significance. In most instances the effects of these compounds on humans, livestock, birds, fish, etc. are not known. It might be mentioned that the biological action of most chemicals applied to plants is poorly understood, Following application of a chemical a plant may die, may become chlorotic (lose Chlorophyll), may grow abnormally, may shed certain organs (leaves, flowers), or undergo some other change in growth pattern. It is not known, however, whether the observed effects are due to the compound originally introduced in the plant or to some metabolite developed within the plant. The active molecule may not be directly related to this introduced chemical but may be a molecule formed by some metabolic pathway activated or repressed by the introduced chemical.

It is likely that the fate of a particular chemical in a plant such as wheat may be different from that in spinach. In wheat it is the grain that is harvested and used for food while in spinach the leaves are used. Also the conditions under which plants are grown will influence plant metabolism. Thus moisture stress, mineral nutrition, temperature and intensity of radiant energy all influence plant growth and development.

Whatever may be the fate of the applied chemical within the plant, the possibility exists that the altered metabolism, or some specific metabolite, will have an influence on human health. It only is recently that techniques have become available for studying this problem. The techniques of chromatography, spectrophotometry, mass spectrometry, NMR spectrometry, and so forth now enable one to isolate and identify biologically active molecules. Once active molecules have been identified they can be synthesized and tested for biological activity in a number of test organisms.

From what has been said it is clear that this is a complex problem; one that needs a continuity of research effort over a period of years. A short "crash" program will not be productive. The problem is typical of many biological and biomedical research problems that require research over a period of years before significant results can be obtained. Agencies responsible for funding research must be aware of the long-term nature of a great deal of modern biological research and be prepared to commit adequate funds over a number of years. Also the plant chemical problem illustrates another aspect of modern biological research - the need for expensive and sophisticated equipment. Most university laboratories have not been able to keep up with inflation and the increased costs of maintaining equipment now on hand. The purchase of new equipment is extremely difficult. Here again agencies funding research must be aware of the increased cost of carrying out research and support the investigation adequately.

2 October 1978

STATEMENT TO PANEL 1A
FUNDAMENTAL RESEARCH

BY

Robert M. Bock
American Society of Biologists and Chemists
University of Wisconsin
Madison, Wisconsin

The five year plan should articulate the principles by which priority for support can be judged in diverse areas of fundamental research. In every case, the clear plan, based on sound background of theory and experiment, must be presented. The credentials and productivity of the research performers is important to weigh.

Some devoted defenders of basic research, in their zeal to defend innovation and freedom, paint a picture of freedom from accountability which is not a necessary component of basic research. The sound proposal, the record of productivity and the progress in achieving the declared objectives are all scrutinized in the intense competition for research support. In proper degree, this scrutiny and pressure is healthy for research. However, if the probability of success becomes small or if clear and valid principles are lacking or ignored in the overall budget, proposal review or grant administration process, the nation suffers and its funds will not be optimally expended.

The budgetting and funding processes developed in this planning process should have features to insure quality and to establish priority and balance. The criteria must either recognize the differences in the theoretical basis and stage of development of various fields. Whether theory and basic knowledge at hand permit highly specific plans and protocols or only a rational route by which data can be accumulated and evaluated, the criteria must select the highest quality science and provide a basis for establishing priority when compared to other diverse fields in basic science.

PUBLIC TESTIMONY
TO
FUNDAMENTAL RESEARCH PANEL
OF THE
NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES
3 OCTOBER 1978
BY
COLONEL ROBERT E. GLASGOW, MA
PRESIDENT
DOWN'S SYNDROME CONGRESS

DISTINGUISHED PANEL, LADIES AND GENTLEMEN I SPEAK TO YOU TODAY AS A PARENT OF A DOWN'S SYNDROME CHILD, AND PRESIDENT OF THE DOWN'S SYNDROME CONGRESS. THE DS CONGRESS IS A NATIONAL ORGANIZATION WITH MEMBERSHIP IN EVERY STATE AS WELL AS SOME FOREIGN COUNTRIES. FOR THE SAKE OF TIME I HAVE ENCLOSED A LISTING OF THE PURPOSES OF OUR NOT-FOR-PROFIT ORGANIZATION.

LATE IN AUGUST OF THIS YEAR I SUBMITTED A COPY OF OUR 17 APRIL 1978 TESTIMONY TO THE HOUSE AND SENATE APPROPRIATIONS COMMITTEE TO DR. FREDRICKSON FOR CONSIDERATION IN YOUR MOST WORTHWHILE AND CHALLENGING ENDEAVORS.

MY REVIEW OF YOUR DRAFT DHEW HEALTH RESEARCH PRINCIPLES AND THE SUMMARY OF GENERAL THEMES OF PUBLIC SUGGESTIONS REGARDING HEALTH RESEARCH PRINCIPLES AS WRITTEN IN THE SEPTEMBER 15, 1978 MEMORANDUM TO REGISTERED PARTICIPANTS RESULTS IN THE FEELING THAT THERE IS NOT MUCH MORE TO ADD TO WHAT YOU AND WE PERCEIVE AS IMPORTANT. BASIC GENETIC RESEARCH IS ESSENTIAL TO BIOMEDICAL ADVANCES WHICH WHEN DIRECTED TO APPLIED RESEARCH CAN IMPROVE LIFE FOR THOSE DIRECTLY INVOLVED IN THE RESULTS. (THE DOWN'S CITIZENS, THEIR FAMILIES AND SOCIETY)

IT IS EXTREMELY IMPORTANT THAT RESEARCH NOT BE STYMIED DUE TO LACK OF

THE STATE OF ART AND THAT BASIC RESEARCHERS BE AWARE OF NEEDS BEYOND THE IMMEDIATE SCOPE OF THEIR MISSION.

IT IS IMPORTANT TO DEVELOP A MEANS OF DETERMINING WHAT IS IMPORTANT RESEARCH, OF SELECTING THOSE GRANT REQUESTS TO RECEIVE FEDERAL FUNDING AND THAT A COORDINATED CENTRALIZE EFFORT OR OFFICE ORCHESTRATE LONGITUDINALLY EACH MAJOR AREA OF RESEARCH SUCH AS BASIC RESEARCH INTO CAUSES OF DOWN'S SYNDROME AND THE MANY OTHER AREAS IDENTIFIED ON PAGE 2 OF ATTACHMENT 3 TO YOUR 15 SEPTEMBER LETTER. ONCE RESEARCH IS IDENTIFIED AS NECESSARY OR IS UNDER WAY THE SCIENTIFIC AND PUBLIC COMMUNITY MUST BE INFORMED OF THESE EFFORTS.

I HIGHLY INDORSE SENATOR KENNEDY'S STATEMENT TO NIH IN HIS APRIL 3, 1978 ADDRESS: "PUBLIC PARTICIPATION IN SETTING RESEARCH PRIORITIES IS THE RESEARCH COMMUNITIES' BEST DEFENSE AGAINST THE ADOPTION OF SHORT-SIGHTED AND MISGUIDED RESEARCH POLICIES." LAY PERSONS, THE CONSUMER, SHOULD BE A PARTY TO YOUR EFFORTS. WE HAVE A STAKE IN WHAT YOU (HEW) DO AND WHAT RESULTS ARE OBTAINED. ACCORDINGLY, WE WILL NOT TREAT MUTUAL EXCHANGE OF IDEAS LIGHTLY.

THE DOWN'S SYNDROME RESEARCH Comittee CONGRESS HAS DEVELOPED A PAPER FROM A SURVEY OF PARENTS, PHYSICIANS, EDUCATORS AND PSYCHOLOGISTS KNOWLEDGEABLE IN THE FIELD OF DOWN'S SYNDROME. THE DOCUMENT THEY DEVELOPED WHEN APPROVED NEXT MONTH BY OUR BOARD OF DIRECTORS ESTABLISHES RESEARCH PRIORITIES OF THE DOWN'S SYNDROME CONGRESS. I REALIZE WE ARE NOT DISCUSSING PRIORITIES TODAY AND THAT NOT ALL THE GOALS IN THE PAPER APPLY TO BASIC RESEARCH. WHEN YOU GET TO PRIORITIES PLEASE CONSIDER OUR PAPER. IT IS OF GREAT IMPORTANCE TO US AND WE FEEL IT IS IMPORTANT TO THE RESEARCH COMMUNITY TO HEAR OUR IDEAS. YOU EACH HAVE BEEN PROVIDED A COPY.

BASIC RESEARCH IS THE MAJOR EFFORT THAT MUST BE CONTINUOUSLY UNDERTAKEN SO THAT SOMEDAY WE, SOCIETY CAN FIND OUT THE CURRENT UNKNOWNS AND DEVELOP MEANS OF CORRECTING AND PREVENTING GENETIC ERRORS.

TESTIMONY BY DR. J. W. GRISHAM TO THE PANEL ON FUNDAMENTAL RESEARCH

NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

Bethesda, Maryland - October 3-4, 1978

My name is Joe W. Grisham. I am a physician-educator and basic research scientist at the University of North Carolina at Chapel Hill, where I am Professor and Chairman of the Department of Pathology. In my testimony before the Panel on Fundamental Research, I represent officially the Association of Pathology Chairmen, an organization of the academic pathology departments of the United States and Canada, whose Research Committee I chair.

Health care today is based on the operation of advanced technology of massive proportions. This high technology, in turn, is founded on the elucidation and application of scientific insights gained from fundamental research into disease mechanisms. The vital linkage between basic research and useful applications is not a new perception, having been clearly enunciated some three hundred and fifty years ago when B~~e~~acon wrote, "First endeavor to discover true causes and axioms, seeking for light not fruit. Axioms supply practice with its instruments and draw along trains of useful work". The relationship between fundamental research and applied technology is absolute. Without a steady enlargement of the base of fundamental scientific knowledge into disease mechanisms, the current technologies applied to diagnosis, treatment, and prevention of disease become obsolete. Attempts to develop technologic applications unsupported by detailed scientific insights lead to expensive impasses or to the deployment of apparatus and materials whose value or hazard to society is not known. Current practical programs in environmental regulation and cures for cancer are of limited success and enormous expense because basic knowledge is inadequate. The stock-pile of fundamental knowledge rarely contains everything necessary to solve any complex problem, and it is impossible to perceive in advance exactly what basic insights are required. Limitation of fundamental research to those areas that seem to be most relevant to national needs at a particular time is wasteful and frequently hazardous. Basic research targeted too narrowly to current needs leaves us unprepared to meet unrecognized future problems.

Continuity of basic research requires continuity of support. Although the momentum of prior fundamental research accomplishments produce important technologic advances well into the future, the current decline in funding will have long-lasting effects and the results of a sustained decline will be impossible to correct quickly. Since 1968, federal support for fundamental research has declined steadily both in constant dollars and in proportion to the gross national product. Unpredictibility of scientific support has posed almost as serious a problem as has its absolute decline. Sudden changes in agency policy as to favored targets has led to inefficient phasing out of projects on short notice. Because of the resultant contraction of fundamental research, the scientific base that undergirds technology in several important areas of health care already is thin. This atrophy of the scientific base of health care technology can be corrected only by providing more substantial, stable, and less restricted support of projects, equipment, and investigators in areas of fundamental research.

At the same time that funding for basic research has declined, regulations pertaining to the expenditure of these funds have become more complex, administrative burdens have increased, and peer review has been threatened. Too much of the scientist's time is required in applying for funds and in justifying, accounting, and reporting on their use. Furthermore, funding of equipment and facilities and for the training of young investigators has been most severely limited. This distorted emphasis has led to the situation in which the objectives of funded programs cannot be accomplished efficiently, because of obsolete equipment or lack of innovative, energetic investigators. Peer review for scientific excellence has been compromised by forcing review panels to make decisions of merit too finely, so that opinions partly reflect aspects such as target and the magnitude of requests for equipment.

Several changes are required to reverse the erosion of fundamental research capability:

1. An absolute increase in the amount of amoney directed to support fundamental research is needed to overcome the nearly fifteen percent decline during the past ten years.

2. The amount of money should be sufficient to fund at least fifty percent of the applications approved by review panels, to restore the integrity of peer review.

3. Specially targeted basic research should be reduced drastically, with research initiatives determined by the individual investigator on the basis of his or her expertise and interest.

4. Mechanics of funding should be altered so that more stable funding can be efficiently accomplished.

5. Funding of facilities and equipment should be restored to the former level of about eleven percent of total research allocations, to allow use of the most capable, sophisticated techniques. Equipment should optimally be supported from a source separate from that used to fund projects, and requests for equipment should be reviewed by a panel not evaluating the scientific merit of research proposals.

6. Support for graduate and postdoctoral fellowships should be increased and their use should be made less potentially punitive, to partially restore the needed supply of young investigators.

7. Regulations pertaining to administration and management of grants must be simplified without compromising public accountability, to allow highly trained investigators to focus their talents on scientific objectives.

Thank you, Mr. Chairman, for the privilege of presenting these viewpoints.

Testimony Presented to the Panel
on Fundamental Research
Dr. John I. Nurnberger, Professor
Indiana University Medical Center

National Conference on Health
Research Principles

October 3, 1978

I have only a brief comment about psychiatry and psychiatric research and its relationship to basic research.

Over the last three or four decades there has probably been more clinical investigative work on schizophrenia than on any ten other phenomena that disturb human beings. That is a lot of work, a lot of papers, a lot of seeming clinical research contributions. The thing that is horrifying about the whole business is that the vast majority of these clinical research investigations on schizophrenia were in fact not on schizophrenia. If there had been a sufficiently serious and in depth basic research base, I think, for many clinical investigators, this might not have been so. But it was so, and most of the alleged investigations in--70 percent of the instances or so--which were presumably on identified schizophrenic patients, were rather in fact on anxiety, on diet, on social environmental factors, family interactions generally, and let us say, general family and genetic factors, but not specifically on schizophrenia.

One of the things that I am sure shocks us, over and above the substantial amount of research funds that have been invested in some of these researches, is the fact that so little attention has been directed, as it should have been, towards the elaboration of specific, definitive clinical criteria for the identification of such phenomena. If you asked a basic laboratory scientist what he was working on, he might say, "Well, there's some kind of an enzyme in there, I'm not sure what it is, or precisely what its characteristics are, but it's kind of fun to kick it around a bit." Of course, he actually would not say that, because it would not be good for business.

The psychiatric investigators who have explored schizophrenic disturbances have not said that either, but they might have in many instances, because of the almost total indifference, until recent years, for the use and application of specific clinical criteria for identifying what they are working with. At least there have been behavioral criteria, palpable, sensible criteria that have been evolved by at least two groups in recent years that have made research more meaningful in this tremendously important area. That is something which is in fact just now beginning, but should have been occurring and producing meaningful data, and rewarding us with other than empirical observations and empirical data for many, many years. But this has not been the case until very recently, and so my plea in talking about fundamental research and clinical research is a plea for a fundamental research basis for psychiatry.

TESTIMONY BEFORE THE NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

October 3, 1978

(A.) I am Dr. Howard Brinkley of the Department of Zoology, University of Maryland at College Park, Maryland. I am the Washington representative of the Society for the Study of Reproduction, a North American Society, with an international membership of over 1500. Our Society's objective is to foster research and training in Reproductive Biology. The Society membership attains these objectives by sponsoring an annual meeting, where research reports and symposia are presented and by publishing the highly acclaimed scientific journal Biology of Reproduction in which advances in research are reported.

(B.) I have been authorized by the Board of Directors of the Society for the Study of Reproduction to heartily endorse the principle that "a national commitment to fundamental research is essential to meet the full range of public health expectations".

(C.) Traditionally, advances in fertility regulation or improved fertility have derived from fundamental discoveries resulting from investigator initiated research which flourished in a stable environment free from external influences. Frequently, these fundamental discoveries have been made prior to the recognition of a national need. For example, the discovery that ovarian steroids control pituitary gonadotrophin secretion was made by R. K. Meyer and his collaborators in 1930. This discovery occurred 28 years prior to the 1958 development of the first orally active contraceptive for the human female by Pincus and colleagues. Thus, the fundamental discovery forming the theoretical basis for the world's first modern, systemic contraceptive was the result of investigator-initiated research performed on laboratory animals nearly 3 decades prior to its application to an urgent human health problem.

(D.) Failure to develop an oral contraceptive soon after this fundamental discovery was not caused by the scientists disregard for the application of the knowledge. Rather, it resulted from the lack of an orally active synthetic ovarian steroid and because the human population explosion had not been recognized to be a public health problem. Once the national health need was perceived, Meyer's fundamental discovery, made in 1930, found application in 1958.

(E.) Meat and milk production have been increased worldwide by the artful application of our fundamental knowledge of gamete physiology, test-tube fertilization and embryo transfer. This same store of fundamental knowledge so long employed to increase animal protein production now shows promise of being used to combat specific types of sterility in the human female.

(F.) Members of the Society for the Study of Reproduction are concerned that Investigator-initiated research which led to the aforementioned discoveries and their subsequent application to public health problems is being threatened. For example, Federal legislation authorizing many NIH programs is allowed to lapse frequently, thus creating chaos in the research establishment. Insistence that basic research be surrounded by and related to an area of application research stifles the individual initiative and creativity required to discover fundamental concepts. The constant reassessment of our national needs and subsequent earmarking of dollars for specific areas of research of immediate concern frequently diverts limited funds away from one area into another. Unfortunately, experience proves that it is impossible to predict what fundamental research will find application to the yet unidentified public health needs. We are alarmed by the curtailment of funds and the cyclic variation in funding available for research in Reproductive Biology.

(G.) The bulk of financial support for the reproductive sciences is now derived from governmental sources. The governmental share increased from 44% in 1965 to 69% in 1974. Concomitantly, the share coming from private philanthropy declined from 22% to 14% while the proportion contributed by the pharmaceutical industry was cut more than half from 34% to 16% (from Greep, Koblinsky and Jaffe, Reproduction and Human Welfare: A Challenge to Research, MIT Press, Cambridge, MA, 1976). Consequently, any perturbation in governmental appropriation sends violent reverberations throughout the Reproductive Biology research establishment. That this "boom and bust" cycle exists is seen in the fact that the percentage of approved grants funded by the Center for Population Research of the NICHD has varied recently from a high of 57.8% in 1972 to a low of 25% in 1977. Obviously, it is impossible for researchers to establish and maintain a consistent attack on a scientific problem in the face of such instability.

(H.) In summary, we recommend that a reasonable level of long-term and stable financial support be made available for investigator-initiated research. We are opposed to the concept that basic research must be surrounded by and must relate closely to an area of applications research.

(I.) The Society for the Study of Reproduction thanks you for the opportunity to testify at the National Conference on Health Research Principles.

Dr. Roger A. Gorski, President
SSR
Department of Anatomy
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Approved by the Board of Directors
Society for the Study of Reproduction
October 2, 1978

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A LS
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AMYOTROPHIC
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STATEMENT BY THE AMYOTROPHIC LATERAL SCLEROSIS SOCIETY OF AMERICA TO THE PUBLIC FORUM HELD OCTOBER 3 and 4, 1978, AT THE NATIONAL CONFERENCE OF HEALTH RESEARCH PRINCIPLES, NATIONAL INSTITUTES OF HEALTH, BETHESDA, MD.

Amyotrophic lateral sclerosis (ALS) is a progressive paralytic disease in which the motor nerve cells of the nervous system cease to function and sometimes die so that the muscles supplied by such nerve cells go out of control and become paralyzed, even stopping the breathing, swallowing and speaking functions.

- It usually strikes mature persons in the prime of life;
- Its cause is unknown;
- The average course is three to four years from diagnosis to death;
- Medical science has developed no therapeutic treatment; and
- Very little research has specifically been pointed to ALS.

WHAT IS THE IMPACT OF ALS?

It has been estimated that there are between 10,000 and 30,000 cases of ALS at any one time. Because of the early termination of ALS patients, it is believed that ALS may well present an incidence as high as that of multiple sclerosis and four times that of muscular dystrophy, both of which diseases are receiving many times the research effort of ALS.

The impact on ALS patients and their families is devastating. To be told that one has a terminal disease, that his life will terminate within three to four short years, that the cause is unknown, that there is no treatment of therapeutic value, and that little is being done on ALS by medical researchers leaves the ALS patient small room for hope.

It is bad enough for the family and friends to see a loved mother, father, relative or friend struggle for life with the ever-encroaching and debilitating effects of ALS. It is, of course, worse for the patient. The anguish of watching a loved one gradually being devoured as the disease moves to its final victory decimates and demoralizes families. It usually bankrupts the ALS family and creates a feeling of hopeless despair shared by the patient and loved ones alike. There is no disease known to medical science that takes a greater toll both psychologically and spiritually. Considering the loss of productive and earning capacities, together with the cost of custodial and symptomatic care, the total cost of ALS to society may well exceed one billion dollars annually.

HOW WELL IS THE HEALTH CARE SYSTEM COPING WITH ALS?

There is no known prevention for ALS, and little research money and time has thus far been devoted to its etiology. Medical scientists believe that the answer to ALS may well lie within the following categories or methodological innovations:

- Normal biology of motor neurons (biochemistry and physiology);
- Neuronal degeneration and response to injury;
- Neurotropic factors, nerve growth factor, neuronal DNA repair and hormonal factors;
- Motor system transmitters;
- Axoplasmic flow and receptor activity of motor nerve terminals;
- Influences of muscle, nerve terminals, sprouting on integrity of neuronal function;
- Environmental toxins that affect the motor system;
- Viruses causing chronic neuronal disease;
- Neuron specific antigens and immune responses to normal surface antigens or altered neuronal membranes;

- Pharmacology of drugs influencing motor neuron functions and spasticity;
- Cell culture systems involving neurons and neuron-muscle interactions; and
- Cell separation procedures.

These categories of research are not being exhaustively pursued, and until funding adequate to follow not only these research possibilities but new leads as well becomes available from the Federal budget,but also from private philanthropic sources, there exists little hope for the prevention of ALS. A few more million dollars now in basic research may well pay giant dividends in terms of life quality as well as economic savings for our Federal government and its patient citizens. Holding back research funding from motor neuron disease (ALS) because of the lack of viable clues is now untenable.

The ALS Society in its three years of existence has funded over $1,000,000 in research. Our immediate goal is $2.5 million annually. At this time, the Federal government has not done much more than this in its ALS research effort. Is it too much to ask for the Federal government to allocate five or even ten times the amount now being budgeted for ALS research? In such an eventuality, the Federal government would still be funding for ALS research less than the ratio between private private and public expenditures for most other disease categories. How much longer must the ALS patient wait for a fair share of the Federal medical research funding and its concomitant measure of hope?

The Congress of the United States, in November 1977, recognized the destructive impact that ALS has on a significant portion of our citizens and, accordingly, passed Senate Concurrent Resolution 26 which directs that national attention be focussed on the need to find a cure for this terrible disease. The Congress has now supported the ALS research program by increasing the FY 1979 appropriations by some 50 percent, from a little over $2 million in FY 1978 to a little over $3 million in FY 1979. The funding for NINCDS, overall, will be increased substantially. The Senate-House conference is now meeting and it appears that the House allowance of $189 million and the Senate allowance of $225 million may yield an agreed-upon amount of some $210 million, an increase of over $40 million over the FY 1978 appropriations of $171 million. In view of this substantial increase in available funds for basic and clinical research, it is recommended that NINCDS expand its health services research program as well as its clinical applications for ALS and other neurological diseases.

Respectfully submitted,

Elmer Cerin
Area Vice President

FUNDAMENTAL RESEARCH

I am Dr. Frank G. Standaert, Chairman of the Department of Pharmacology at Georgetown University. I am here in the place of Dr. Bert LaDue, President of the American Society for Pharmacology and Experimental Therapeutics.

I shall speak from the viewpoint of the university investigator doing fundamental research. I have no hesitancy in asserting that this kind of activity is required for advancement in my fields: pharmacology and the development of new and better drugs for treating human disease. In the past many drugs were developed from compounds known from antiquity or were discovered by accident. Now our opportunity for developing drugs via these routes is greatly diminished because we have used up the information we inherited from previous generations. In the future, improvements in drug therapy will depend upon our ability to rebuild our store of basic knowledge. We need new drugs because they are the only practical means to treat or prevent the diseases which afflict billions of people, but to get new drugs we need a new and better understanding of basic physiologic processes and the means by which chemicals can influence these to overcome disease.

Gaining this fundamental knowledge requires research which is both long range in planning and comprehensive in scope. It cannot be done without adequate long range support for research into the basic phenomena of life. By its nature this fundamental research takes time because it involves challenges which have been seen in people's minds, but for which there are no defined pathways of research or predictable outcomes. It also requires some security for the investigator and his/her laboratory. Investigators need the opportunity to explore risky but potentially valuable leads. They also need time to think; to experiment and to synthesize thoughts and data into comprehensive insights into basic phenomena.

This kind of research is very difficult to do today. Most grants are for three years, and the application writing and review process consumes at least a year. This means that investigators rarely have more than one and one-half to two years to do creative work. The rest of the time the would-be researcher is distracted by the need to raise money. He/she is never free of anxiety about losing support for the laboratory in the future.

The problems caused by short term funding are compounded by the limited amount of money for basic research. In recent years only ten to twenty percent of approved grants have been funded. In this circumstance the investigator is forced to do three things: 1) live in fear that support for the research and perhaps for his/her salary will terminate before there is a chance to complete the work; 2) do short range, quickly publishable work in the hope that this will lead to the award of a new grant; 3) write three to five applications, in the hope that one will be successful. All of these are counterproductive for fundamental research.

I ask, therefore, for a plan which provides adequate support for fundamental research. I also ask for a plan which gives stable, dependable support via mechanisms which encourage investigators to do their primary jobs: conduct research. At a minimum, I think this calls for a return to five and seven year grants. Even better would be a mechanism for partly institutionalizing extra mural support so investigators can work with some assurance that they can undertake long range research and will be free of the fear that their research, and perhaps their livelihoods, may end with the termination of a grant.

Name: Harlyn O. Halvorson, MD.
Affiliation: Association of American Medical Colleges and American Society for Microbiology
Panel: FUNDAMENTAL RESEARCH

I am Harlyn Halvorson, Director of the Rosenstiel Basic Research Center, Brandeis University. I am pleased to appear before this Panel to present the views of the Association of American Medical Colleges and the American Society for Microbiology on fundamental research in the biomedical and behavioral sciences. The Association and the American Society for Microbiology believe that one of the most important challenges facing the biomedical and behavioral research community at the present time is determining the appropriate balance between exploratory research on the one hand and the understandable desire of Congress and the public to accelerate the transfer of ideas gained from research to the care of the sick and the conquest of disease on the other hand. Three broad categories of research may be distinguished: fundamental, clinical and targeted research. Each form of research is valuable in its own right and each deserves continued support.

Fundamental or basic research is exploratory, usually long term and undifferentiated, and is rarely targeted, programmed or centrally directed. It depends on investigator-initiated ideas and its practical application is often unpredictable. Nevertheless, basic research is essential to the development of new fundamental knowledge upon which applied research and development are based. Historically the application of knowledge from basic research to practical problems of health has proved the importance of this position. There are numerous examples of the value of basic research in the solution of key health problems and some of these have been clearly described by Drs. Comroe and Dripps in their 1974 article in Circulation Research.

It cannot be emphasized too strongly that the discovery of new fundamental knowledge through basic research remains the foundation for progress in the understanding of disease processes and their ultimate prevention and/or cure.

Basic research is the critical first step in this process and, in the short term, the effectiveness of targeted programs depends strongly on basic research. Despite the great scientific progress of the last 20 years there remain demonstrable gaps in knowledge and areas of ignorance. For this reason basic research must be awarded a high priority.

A competition for funding has developed between fundamental, applied and targeted research -- the latter as represented particularly by the tendency to direct research efforts along disease or organ-system oriented program lines and to establish research and demonstration centers targeted on specific diseases. The Association's and ASM's first recommendation therefore is -

- The Federal establishment as the principal provider of research funds should recognize the need to assure stability and an appropriate balance among basic, applied and targeted research.

The financing of biomedical and behavioral research should also be considered in terms of its sources. For many years the Federal government has funded about 60% of the investment in biomedical and behavioral research and development (primarily in the form of support for research), industry has funded 25 to 30% (primarily in support for development activities) and state and private sources account for the remaining 10% to 15%. Even though this arrangement is complex, it has worked well and the public has benefited from the research and development process. The nation's biomedical research endeavor has been very productive in the last three decades but much better understanding of the fundamental nature of health and disease must still be achieved through research. Thus, it will be necessary for the foreseeable future to continue an emphasis on research and the Federal government, as in the past, is the logical sponsor for the primary research role.

The magnitude of the Federal involvement in biomedical and behavioral research is such that it is unlikely that any other organization, public or private, can provide the necessary impetus should Federal support falter. The record of NIH support to basic research in the past is unexcelled. However, in recent years short term goals have been increasingly emphasized and the impatience of the public, as perceived by their Congressional representatives, for the transfer of knowledge to clinical applications has been translated into legislative mandates for targeted programs. While impatience is understandable, it has been clearly pointed out that clinical advances depend on the often uneven but stepwise discovery of basic knowledge. These observations provide eloquent evidence for the value of vigorous programs of basic research of the highest quality and maximum breadth. Such programs should be maintained in each Institute of NIH and ADAMHA. The basic mechanism of support for this type of research should remain the traditional investigator-initiated grant and program project grants. Only rarely are other funding mechanisms appropriate for support of basic research.

The Association and the Society therefore recommend:

- To protect their health and improve management of their illnesses the American people should continue their commitment to biomedical and behavioral research supported from diverse sources. Stable funding should be assured and adjusted annually to reflect research needs and costs and to permit exploitation of new research and development opportunities. The Federal government's primary but not exclusive role in this area is affirmed.

- AAMC and ASM strongly endorse the investigator-initiated project grant as the most appropriate mechanism of support of basic and applied research. Consequently, investigator-initiated projects should have priority over centrally directed funding mechanisms which are more appropriate for clinical trials, research/demonstration centers and other targeted activities. Any erosion of support for investigator-initiated activities, regardless of cause, should be immediately remedied.

My name is Dr. William R. Cunnick, Jr. I am Vice-President and Deputy Chief Medical Director of the Metropolitan Life Insurance Company and I also serve as President of the American Social Health Association, a national voluntary organization dedicated to the control and eventual elimination of venereal disease.

To begin, may I express my sincere appreciation, and that of the board and membership of the American Social Health Association, for this opportunity to present our views at this National Conference on Health Research Principles.

Over the course of my 25-year tenure as a physician and medical administrator, I've witnessed the problem of the control of venereal disease - more modernly termed sexually transmissible disease -- change in many ways.

> What was once seen singularly as a syphilis and gonorrhea problem is now recognized to be much broader, encompassing diseases such as nongonococcal urethritis and cervicitis, trichomoniasis, genital herpes, group B streptococcal disease, cytomegalovirus infection and hepatitis, to mention only a few. In all, over 20 diseases are now known to be sexually transmissible.

What were seen principally as acute care problems and only rarely as having chronic characteristics, are now clearly seen as diseases of major and progressive pathological consequences.

What was once thought of as an adult health issue is now recognized as being an extremely important perinatal health issue.

What once presented virtually no treatment problem now presents a significant one -- both in terms of diseases for which no cures exist, and curable diseases for which treatment failure has become common.

To place the sexually transmissible diseases problem in present context, I offer the following:

What were perceived to be relatively low levels of incidence (several hundred thousand), now are dwarfed by contemporary STD incidence estimates of over 10 million cases.

Several of these entities -- most notable genital herpes, CMV infection and hepatitis -- are viral in etiology and hence incurable and difficult to control. Mass screening techniques for reservoir identification and control purposes exist for only 6 of the over 20 sexually transmissible diseases.

Proven vaccine preparations exist for none. In addition to these stark dimensions of the problem, the STD's represent an actual and growing source of morbidity and mortality -- principally among women and neonates. CMV is now the most common viral cause of mental retardation in newborns, surpassing even the rubella virus in this regard. HSV2 is a significant threat to infected women as an associative factor in cervical carcinoma, and to offspring of such women, who can acquire this virus during parturition with devastating results. Neonatal group B streptococcal disease debilitates or kills significant number of infants each year. Gonorrhea is estimated to pathologically sterilize 100,000 women of childbearing age each year. Nongonococcal cerviçitis is suspected as a source of pathological sterility, and chlamydia trachomatis recently has been cited as an etiologic factor in infant pneumonitis. Conservatively, it is estimated that 5 percent of all newborn infants are exposed to this organism.

In addition to being a significant source of major medical consequences, sexually transmissible disease represents a major medical cost factor with respect both to acute and long-term care. This cost factor has been calculated by the United States Public Health Service, the American Social Health Association and others to range from $800 million to $1 billion annually.

These facts, then, comprise reality of the epidemic of sexually transmissible diseases which face us -- certainly a reality which calls for solutions.

Where do the potential solutions lie? Where are the significant opportunities?

Without equivocation it can be said that research alone holds the long-term potential for solving the sexually transmissible disease problem. Obviously, effective vaccines would be ideal, - and their prompt development is imperative. But faced by a problem as diverse as this one, we should also be looking to short-term innovations -- actions that can fill present voids and help bring about a modicum of control. Research leading to better screening tests, better treatment agents, etc., is required. Starting from a research base as small as the present STD base, we must ensure the development of adequate numbers of trained, qualified researchers to devote time and talent to the tasks at hand.

How much of this vital agenda is being addressed?

It is our view that STD research is being underserved within the NIH. This view is based upon the apparent low priority ascribed to STD research as evidenced by the inadequate federal allocation of only $6 million per year. Nowhere can we find a justifiable balance between an STD research investment of $6 million annually, compared with the magnitude and severity of these diseases, and their annual morbidity costs of $1 billion.

How can we possibly hope to facilitate a thoughtful process of scientific inquiry, and search for both medium- and long-range solutions to epidemic STD on an annual total budget of just $6 million?

We must admit that we can't. We can no longer afford to pay what amounts to lip service to this growing menace. We must properly stimulate and fund the research community or we undoubtedly will be facing an even greater problem in the future.

We would therefore recommend that STD research be made an immediate priority of this nation and its principal research vehicle, the NIH, and be allocated resources commensurate with its priority status.

The consequences of STD fall most heavily on young people, women, and children, an essentially powerless and silent constituency. This is your opportunity to speak for them.

October 3, 1978

Testimony presented to the panel on Fundamental Research at the National Conference on Health Research Principles

Joyce Pennington, M.A.
Secretary, Bureau of Research
American Osteopathic Association

The American Osteopathic Association fully approves the recommitment expressed by the President and the National Insitutes of Health to fundamental research. The decline in support for basic research during the last ten years has been discouraging to the osteopathic profession, particularly since during this same period both the number of and the enrollment in osteopathic colleges have more than doubled.

The development of colleges during this period of decreased research funding has had serious effects. Many young investigators have been employed by the colleges in various basic science and clinical departments. Most of these teachers trained at institutions with strong research interests and capabilities. However, the osteopathic colleges now employing them have not been able to support their research interests because the decreased federal funding during this period has not allowed the colleges to develop their research facilities, nor have the funds been available for support of the new investigator's research projects.

In addition, over a longer period of time the quality of teaching in these colleges will be affected adversely by the lack of research funding. Involvement in research projects requires teachers to keep abreast of recent developments in their fields; thus, the quality of teaching may be enhanced. In addition, doctors who have been exposed to research during their training can evaluate more effectively research developments which occur throughout their careers and can better apply research findings to the clinical problems they encounter. We must also insure that we continue to train enough researchers to maintain our resources of basic scientists in future years.

The American Osteopathic Association fully supports the development of a "five-year plan" to direct funding and emphases in research. New institutions and investigators cannot compete with large established research centers when the application of research dollars skips from one popular cause to another: they cannot submit good research proposals and adapt research facilities as quickly as large research centers. However, good research is often conducted by newer institutions and/or investigators.

New institutions and investigators must be assured of support for more than a one-year period in order to produce sound research and develop research facilities. Researchers must conserve their own limited resources of time and energy: to begin a research project for which there is no assurance of adequate funding over an adequate period of time is not "cost effective" for either the researcher or the institution supporting him.

The osteopathic profession was reminded recently of the importance of basic research. A research workshop entitled "Neurobiologic Mechanisms of Manipulative Therapy" convened last October. Supported by a grant from the National Institute of Neurologic Disorders and Stroke, 37 scientists and clinicians discussed possible underlying mechanisms of somatic dysfunction and manipulative therapy. Prior to the workshop most of the basic scientists had never considered the implications of their research for these important questions. However, the discussion revealed a great deal of overlap between the interests of the clinicians and the basic scientists. In addition, the conference underlined the importance of interaction between basic scientists and persons who are able to apply their research findings to practical problems.

In summary, the American Osteopathic Association urges that the needs of young investigators and new institutions be considered in the development of any long-term plans. The investment in these people and institutions will pay high interest to the nation in the future.

Speaker: Margarita C. Treviño, R.N., M.S.
Institutional Affiliation: Latino Caucus of the American Public Health Association
Panel: Fundamental Research

INTRODUCTION

Mr. Chairman, Co-panelists, Ladies and Gentlemen:

My name is Margarita C. Treviño, and I am here as president of the Latino Caucus of the American Public Health Association.

The point of reference being used for fundamental research is "the search for knowledge about fundamental processes of biology and behavior." For the purposes of this presentation, I would like to use the term "fundamental" to refer to prioritized and problematic areas of concern related to critical needs in community health research of Latinos in this country. With the exception of one, the areas of concern to be mentioned are basic components of the application of the research process and have a significant role in the planning, administration, delivery and evaluation of effective and humanistic health care systems.

I am interested in emphasizing community health research which will benefit Latinos. I am calling to your attention the urgency (1) to extend and support the focus of investigative efforts to Latinos in our natural environment as the laboratory setting and (2) to develop an increased sensitivity to the need for culturally oriented research.

PRIORITIZED AREAS OF CONCERN/NEEDS/PROBLEMS

DEMOGRAPHIC DATA

Research is needed in demography. There is a critical need to identify and to document who we are demographically as a minority of color.... as a people. Unfortunately we are still faced with demographic data which are traditionally categorized in terms of the White and Black dichotomy. All Latinos, i.e., Mexican Americans, Puerto Ricans, Cubans, etc. are usually lumped together under "White statistics" or columns labled the "Spanish surnamed" or "all others." Our identity has not been established demographically. Our heterogeniety has been seriously ignored and/or glossed over.

We need baseline survey research specifically designed to identify and document who we are demographically (population size, age distribution, sex distribution, population density, economic status, differences in marital status, levels of education, occupatious, etc.).

We need baseline survey research which identifies who we are sociopsychologically and socioculturally. We need baseline survey research to identify differential, intraethnic and interethnic group characteristics of Latinos. At this time, comparative analytical studies are virtually impossible. We do not have basic data banks that are adequate at local, state, or national levels. Demographic data are essential ingredients in community health research.

EPIDEMIOLOGY

We are also in urgent need of epidemiological research. We do not know to what extent we are afflicted by some of the major community health problems facing our society today. Recently, I was unable to secure information on the prevalence of hypertension among Mexican Americans at a local, state, or national level. Yet, we know that hypertension has reached epidemic proportions in this country and that it is a major factor contributing to premature death and/or disability.

We have major needs for epidemiological community health research which addresses Latinos throughout the age continuum.... the specific health needs from prenatal care through the aged population.

We need more information about the nature and distribution of mental health problems, substance abuse, and alcoholism. We need information about the nature and distribution of malnutrition, congenital anomalies, genetically-deficient disease entities, cardiovascular disease, cancer, diabetis, tuberculosis, chronic pulmonary diseases, and communicable diseases. This list is not exhaustive.

Epidemiological research efforts can also help us to acquire new knowledge about the impact of ecological influences on the health status and needs of our people. What are the influences of lifestyles, living conditions, working conditions, etc. on the precipitant health problems of Latino individuals, families, and communities? These questions must be researched.

BEHAVIORALLY-ORIENTED AND CULTURALLY-SENSITIVE HEALTH CARE MODALITIES

A third major problematic area of need is research that will assist in the development, application, and evaluation of behaviorally-oriented and culturally-sensitive health care modalities. This effort is long overdue as we address areas of primary, secondary, and tertiary health care needs in the community.

The "cookie-cutter" approach in existent health care delivery systems particularly designed for the poor and underserved, which constitutes a majority of our people, has not worked for us. Geographic accessability has not amended low service utilization patterns. If one were to dissect the problems of behavioral-cultural barriers to health service utilization, one would find the Latino consumer at a marked disadvantage secondary to language differences, incompatability of provider-consumer expectations, cultural dichotomies, and conflicting value systems.

We value and believe in the importance of health education. We are interested in the promotion of self-help for the Latino individuals, families, and communities. We want to avail our people of the benefits of primary prevention. We want our people to benefit from health-related technology.

The disparities in the health status of Latinos in this country must be amended. We believe that behaviorally-oriented, culturally-sensitive approaches to health care delivery systems are part of the answer. Research efforts are needed to help us move in that direction.

INFORMED CONSENT

Along with the application of any research effort, however small or large, we urge the protection of consumer rights. The knowledgeable consent of Latino consumer-participants in any research activity must be assured to avoid abuse attributable to sociocultural barriers or differences.

MANPOWER TRAINING

In conclusion, we would like to encourage the development and support of Latino manpower training programs in community health research.

CONCLUSION

Research activity is not seen as an end in itself but as a means to effect orderly change. It is recognized as an indispensible process in the redress of human suffering. We are here today to lend support to the development of the Department of Health, Education, and Welfare multi-year strategy for the support of research and to urge that the principles that will emerge from this conference reflect marked specificity to the areas of need affecting the Latino community of this country.

Thank you.

INTRODUCTION

The Association of American Indian Physicians welcomes the opportunity to provide information for this symposium on research priorities. The Association of American Indian Physicians is a national organization of Indian physicians formed in 1971 to improve the life of American Indians, particularly in the field of health. We commend the Secretary for inviting representatives of the American Indian community to participate in this symposium. There are indeed circumstances relating specifically to the health of Indian people which are different from those relating to the rest of the population. Attention to these special circumstances is not only necessary for the protection of the civil liberties of American Indians but also because certain areas of research can be most effectively studied in Indian populations.

"BASIC" vs. "APPLIED" RESEARCH

The Association of American Indian Physicians regrets the necessary division of research into these categories. Such categorization of activities, although understandable, too often leads to competition for resources. There should be no competition between the two, both are needed. Support for an appropriate mixture of each is what is sought.

Research is simply the asking of questions of nature. The value of "basic" undirected research has been confirmed repeatedly. In any national priority for medical research there must be a substantial proportion of effort directed towards basic research. A simple, frequently quoted example of the benefits derived from basic research is that provided by the development of tissue culture techniques for growing viruses. This basic research led directly to the development of a vaccine for polio and other viruses. It is likely that if a major emphasis is demanded for applied research that basic research may suffer. The importance of basic health research applies to Indian people as well as to the rest of the population. We recommend an effort of approximately 60-70% for basic research and 30-40% for applied research.

AN ARGUMENT FOR A SPECIFIC RESEARCH MISSION DIRECTED TOWARDS INDIANS

A number of fundamental differences between Indians and non-Indians require specific examination. These differences may often be more apparent than real, but even so, inquiry into these differences should increase our understanding of disease processes.

For example, it is frequently said that sarcoidosis, a peculiar immunologically-mediated disorder, has never been described in a full-blooded Indian. Conversely, another granulomatous disease, tuberculosis, has had devastating effects among Indian populations. Basic research directed at the granuloma response of Indians would increase our understnding of such disorders.

Bronchogenic carcinoma is extremely uncommon among American Indians, when compared to caucasians. If one understood the underlying reasons for this difference one would have a much better understanding of the etiology of bronchogenic carcinoma.

Epidemiologic and metabolic studies suggest that diabetes mellitus among Indians differs in certain respects from other types of diabetes. Research on Indians has provided important data that increase our understanding of a very prevalent disease.

Degenerative diseases of the blood vessels among Indians, except for those with diabetes, seem to be considerably less prevalent and less severe than for non-Indians. Research into reasons for these differences might provide extremely useful information about the number-one killer and provide understanding of ways to prevent this disorder.

The investigation into possible reasons why gallbladder disease is so much more common among Indians than non-Indians led to investigations of bile salt metabolism which led further to a discovery of techniques for reducing gallstones in certain instances by the use of medications.

Thus there are a rich variety of fundamental differences in disease manifestations between Indians and non-Indians. If there is a moral imperative to carry out research, and we believe there is, then there is a moral obligation to carry out a coordinated research peogram directed specifically at the differences between Indians and non-Indians.

Not only are there intriguing differences between Indians and non-Indians, but there are several intriguing differences between Indian tribes themselves, further stimulating the need for research among Indians. For example, there is a general impression that suicide among teenage Indians is rampant. However, there are some tribes with a high rate of suicide and others with a low rate. Research into the reason for these differences might yield very useful information about the causes and prevention of suicide.

Studies of certain southwestern tribes suggest that there are striking differences in the occurrence of gastric ulcer compared to gastric carcinoma. Again, investigation into the causes of these differences would be very useful for the white society.

There appear to be striking differences between certain tribes in the occurrence of alcoholism and its complications. This has not been systematically studied.

Because of this great variety and because of certain other requirements of Indian people, it would be most appropriate to have a single overall program such as a National Institute of Health for American Indians, whose basic mission is the investigation of these kinds of disorders. There is a precedence for such a program in the collaboration between the National Institute of Metabolic and Digestive Diseases and the Indian Health Service in Phoenix, Arizona. This program is commendable, should receive additional support, and should be expanded into a national, rather than a regional, program. There should likewise be a concerted effort to discover the pharmacologic activity of many of the Indian herbs in use.

POLITICAL CONSIDERATIONS IN THE CONDUCT OF RESEARCH AMONG INDIAN TRIBES

In the present discussion the term "political" is used in its classic sense to refer to people or persons. Because of the unique relatinship of American Indian tribes to the federal government whereby a quasi-sovereign status exists between certain Indian tribes and the federal government there are certain special considerations which must be adhered to in any research program that impinges upon Indian tribes. These have to do not only with the protection of tribal sovereignty, but also protection of the rights of individual Indians. Many of the problems relating to protection of the rights of Indians are more urgent than those for non-Indians, including cultural differences which make exact communication difficult or impossible. Obviously, the same rights that apply to any individual apply to Indians as well. However, it must be emphasized that no research may be carried out in Indian communities without full collaboration by the tribe as expressed through its governing body. Specific mechanisms must be set up which insure that research proposals be funded only after specific collaboration by the trives involved. This collaboration in many instances could take the form of the tribe serving as the responsible agency for the research.

Because of these and other considerations, it is imperative that each advisory council of the National Institutes of Health contain a member of an American Indian tribe. The leadership in this area displayed by the National Institute of Allergy and Infectious Diseases has been noteworthy. The initiative taken by the National Institute Of Mental Health in the establishment of the Center for Minority Group Mental Health is commendable and has proved to be very valuable not only in protecting the safeguards for minorities but in addition has provided an important impetus in the development of research programs carried out by Indians or other minority investigators who have less substantial previous training or experience in the competition for awards. Thus a program has been developed for the upgrading of minority researchers. Such a commendable activity should be spread to other institutes.

SUMMARY

We recommend the representation by members of the Indian community on each advisory council of the National Institutes of Health. This would permit an opportunity for oversight of Institute activities by Indian people.

No research should be carried out in Indian communities without the full approval and collaboration by the Indians themselves. Particular attention should be paid the problems of signing of individual consent forms for procedures.

An institute should be established whose major function is the carrying out of research directed to those aspects of Indian health where epidemiologic data would increase understanding of basic processes of disease.

Statement of Everett R. Rhoades, M.D.
Association of American Indian Physicians
Professor of Medicine and Microbiology
University of Oklahoma Health Sciences Center

Fundamental Research

Philip P. Cohen, U. Wisconsin, Madison

(Representing the American Society of Biological Chemists)

The announced principle of a "national commitment to fundamental research" is inherently logical and continually needs to be emphasized.

Because the extent of our ignorance far exceeds the extent of our basic knowledge, there is an obvious and compelling need to expand our basic knowledge. As recognized, this will require careful selection and adequate support of the most creative and critical scientists. In the HEW structure, this can be best accomplished by increasing the budget of the Institute of General Medical Sciences.

Contrary to widely held misconceptions, new knowledge is not likely, in the present scene of rapid communication, to remain untested for some ultimate benefit. However, the effective and beneficial utilization of new knowledge involves a lag time because of the need to assess its significance and applicability. The lag time will vary with the nature of the application being sought. In some instances, it will be relatively short, as in the application of new principles in analytical technology, diagnostic procedures, etc.; in others it may be very long before certainty of reliability, safety and usefulness can be established. Thus the full benefits of fundamental research can in many instances only be realized many years after the new knowledge has been generated. The public expectations and societal pressure to reap immediate benefits from new knowledge thus reflect a lack of understanding of how science and the utilization of scientific knowledge must operate to the benefit of the individual's health, the environment and our society.

William F. Collins, Jr., M.D., Secretary
Society of Neurological Surgeons

Panel 1 - Fundamental Research

The Society of Neurological Surgeons is composed of neurosurgical residency training program directors, professors and chairmen of medical school neurosurgical units, and other selected neurological surgeons who have or are contributing to neurosurgical education. The Society's main interests include neurosurgical education in its broadest sense. The Society wishes to present the following concepts and suggestions that it believes are relevant to the consideration of fundamental research in the biological sciences.

There are discrepancies in defining basic or fundamental research in the biological sciences. Some believe it is essentially a molecular or submolecular discipline while others believe it is any research that is not clinical. The Society of Neurological Surgeons wishes to stress that fundamental research in the biological sciences should be a continuum from the most esoteric to the most pragmatic and that care be taken to insure the survival of this continuum, for then both the creativeness of need and of the trained investigative mind can be nurtured. It is obvious that we need both to help solve some of the problems that are before us. There is need to seek information not relevant to any known problem in order for us to advance, There is need to get answers to questions that are well defined, to develop methods to solve problems that can help answer such questions and even to answer such simple questions as 'does a drug or a technique work?'. All these areas should fall within the continuum of fundamental research and their diversity demonstrates the need for communication among the many disciplines involved including the clinical delivery of health services. If the separation implied in the differentiations of Panels 1 and 2 of the Conference on Health Research Principles, a separation quite clearly accepted in many forums of biological sciences, allows this continuum of fundamental research to be disrupted, the Society believes we shall all be poorer.

The Society of Neurological Surgeons proposes that the Fundamental Research panel endorse long-term predictable support for the training and career development of scientists in basic biological science disciplines, that this support include predoctoral and postdoctoral areas of career development, and that support of fundamental or basic research projects and goal-oriented research projects have within the concept of their funding the career development of such scientists, particularly during that transitional period from postdoctoral fellowship to faculty or research team appointment. The Society further proposes that support for clinicians in acquiring basic investigative skills is crucial not only for the continuum of fundamental research but also to enhance communication in both directions between the continuum of fundamental research and the needs of the health services community in general. A side issue, but one which the Society feels is quite crucial, is the fact that in the recent past lack of funding for clinicians to acquire basic research skills during training periods has impaired the recruitment of academic surgeons as demonstrated in the recent manpower survery undertaken by organized neurological surgery. Such recruitment is essential for training of future surgeons and for the type of communication which is essential if fundamental research is to reach its maximum potential.

National Conference on Health Research Principles
National Institutes of Health
Bethesda, Maryland
3-4 October, 1978

THE IMPORTANCE OF FUNDAMENTAL RESEARCH IN CHRONOBIOLOGY TO HUMAN HEALTH

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*Spokesman on Fundamental Research for the International Society for Chronobiology

My purpose in appearing before this panel for fundamental research is to call to your attention a relatively new and powerful field, that of Chronobiology, and to focus especially upon the accomplishments and promises of its embedded integrating discipline, Circadian Regulation. The classical integrating disciplines, Evolution, Genetics and Developmental Biology, cut across the conventional strata of levels of organization from the molecular level to levels of complex systems and social structures, and deal with biological time constants of relatively *long* duration.[1] The newest of the integrating disciplines, Circadian Regulation, deals with the phenomenology of minutes and of days, and contains more hard-core rules of general and predictive consequence than any of the others, with the exception of Genetics. These rules to which I refer, the *Mode Rules*, the *Period Rules* and the *Phase Rules* are general for the eukaryotes, are extendable in depth through the levels of organization within a single organism (be it mouse or man), and can be broadly extrapolated phylogenetically.[2] Their significance to the proper understanding of eukaryotic regulation that underlies responsible health care is directly analogous to the signal significance of Max Delbrück's one step growth curve techniques in the origins of molecular biology and of our current understanding of prokaryotic regulation.

There is substantial evidence from the world literature for the importance of this new field: Over the past five years there has been an exponential growth of papers in circadian chronobiology, currently averaging between 10 and 30 per week; the *First* of the celebrated Dahlem Konferenzen in the Life Sciences held in Berlin in 1975 was on circadian regulation; the *First* of the Gordon Research Conferences in Chronobiology was held this past summer, and another is scheduled for 1980 (for which I have been elected to serve as Vice-Chairman).

Spin-offs from fundamental research into applied biology and medicine are already of far-reaching importance. I have time now to name only a few: In Clinical Chronopharmacology, the circadian oscillation responds dramatically to when during the day a drug is taken.[3] If, for example, L-Dopa is consumed before the circadian acrophase for norepinephrine synthesis, circadian dyschronism is induced; taken later, subjects remain euchronic.[4] In Nutrition, phase shifts can be accelerated by programmed consumption of meals that are appropriately high in either protein or in carbohydrate depending upon the time of day.[5] Taken in conjunction with chronotypic imbibition of methylated xanthine beverages (coffee, tea or coke) such menus can alleviate jet lag.[6] In Enzymology and Metabolism, products such as Glycogen and enzymes such as tyrosine aminotransferase are synthesized and/or induced or depleted *chronotypically*, i.e., in a circadian *phase-dependent* fashion;[7] in Cancer Chemotherapy, circadian protocols are more effective than those that neglect the critical variable unit of dose as a function of phase-of-cycle relationships;[8,9] in Aging studies, longevity is a function of the circadian life style.[10,11,12,13] Each of these examples is a product of fundamental research, sometimes initially of the sort to win the coveted Golden Fleece Award of Senator Proxmire.

As in the days of Genetics before Watson and Crick, we know (and can employ with a vengeance) the basic rules and many of the associated molecular and biochemical pathways (including an apparently very general involvement of protein synthesis, of membrane functions and of catecholamine and indoleamine metabolism) but we do *not* know for sure a single mechanism to control this remarkably ubiquitous and powerful property of circadian time keeping. When we learn the fundamental mechanism, we shall have control over it and over the many forms of physiological, behavioral and mental malaise including dyschronism that arise from its malfunction, either from genetic deficiency or from environmental perturbation.

In summary, Chronobiology is a new field, and Circadian Regulation a broad new discipline that parallels Genetics in its import and power. Dealing as it does with the temporal aspects of gene-action, there is no area of human health and preventive medicine that it does *not* touch upon. I therefore recommend that steps be taken to assure that substantial research initiatives be stimulated and encouraged to reveal the fundamental nature of the circadian pacemaker in eukaryotes. Identifiable key areas include the chronotypic manifestation of gene action, of chromosome and of membrane function, of the levels of energy reserves, and of biogenic amines at the cellular and molecular levels. In the future, study groups, review committees, and advisory panels must insist upon the incorporation of an awareness of circadian strategies into all eukaryotic research protocols. Centers of Excellence in Circadian Regulation should be established, and associated with each of these should be a Center for Human Chronobiology to assure early exploitation of fundamental findings. We students of Mark Adams in those early days of the late 1940's at Cold Spring Harbor knew even then through the narrow veins of the T-phages that we were onto a Mother Lode in the Biological Sciences. It would be selfish and remiss of me now thirty years later not to let you my fellow prospectors and appraisers know that in Chronobiology we *are* onto another Mother Lode of at least equivalent significance--this time, one for the eukaryotes.

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Testimony presented by Mahlon B. Hoagland, M.D.
President and Scientific Director, Worcester Foundation
for Experimental Biology, in behalf of the Delegation for
Basic Biomedical Research.

Before DHEW's National Conference on Health
Research Principles, October 3-4, 1978.

During the past ten months a small group of distinguished scientists and surgeons* has been active, in discussions with members of the administration and of Congress, attempting to bring national attention to the importance of basic research. As their spokesman I submit the following comments:

It is abundantly clear to medical scientists and a significant segment of the public that substantial further improvement in the health of the American people, with attendant cost reductions, awaits the acquisition of much more basic biological knowledge about normal and abnormal cell and body function. The major killers and disablers like cardiovascular disease and mental illness, cancer, and arthritis are now the enemies, as once were other equally fearsome ills. But they can be controlled and and defeated by the methods of basic research.

Our optimism and confidence in the effectiveness of basic research is rooted in the history of its accomplishments. Consider: the virtual elimination of all the major infectious diseases; the impact of vitamins and other nutritional factors on human health, including the lengthening of life expectancy; the availability of Xrays for diagnosis and treatment; the ability of women to control their childbearing; organ transplantation and cardiovascular surgery; the successful treatment of Rh disease of the newborn; improvements in treatment of hormonal abnormalities; and the chemical control of mental illness. These remarkable triumphs are the result of the free exercise of individual curiosity, imagination and experimental ingenuity.

Basic research produces the library of knowledge from which applied research borrows to bring help to the suffering.

There is no question that the diseases we now confront present more formidable problems to the scientist than those already vanquished. But it must be remembered that during the last 40 years our knowledge base has grown at an astonishingly rapid pace, presaging early application to the more intractable problems of human disease. Government-supported research in: the structure and function of cellular membranes; the cellular control of gene expression; chemical and viral carcinogenesis; mode of hormone action; immunology; genetics; and neurobiology now hold particular promise for the eventual prevention, cure or control of cancer, cardiovascular disease, genetic disease, arthritis, endocrine disorders, allergic and autoimmune disease and mental illness.

In spite of the overwhelming evidence of the effectiveness of basic science in eliminating and controlling human ills, we as a nation are spending only one-half of 1% (about $1 billion) of our health care expenditure (about $200 billion) on basic research. While the budget of the National Institutes of Health has risen over the last decade, the real dollar support for basic research has failed to keep pace with the nation's potential for doing that research. Our shrinking resources are increasingly directed toward applied "research" aimed at limited, short-term objectives.

At this stage in history our knowledge base is still inadequate to fathom the complexities of cardiovascular disease, cancer, arthritis, etc. It follows that applied research programs capable of providing definitive practical benefits are very limited in number and scope. Yet government continues to experience rising pressure to sponsor premature, scientifically unsound and inordinately costly applied projects.

The U. S. Government has created and generously implemented the most effective device known to man for initiating and nurturing the best in research: the scientist-initiated, peer-reviewed project grant. In recent years this unique support vehicle has found itself in competition with program-project grants, center grants and contracts, support vehicles better suited to bureaucrats than to scientists.

In view of the above considerations we urge the Department to give particular attention to the following in a multi-year plan for health research:

1. A substantially greater proportion of National Institutes of Health funds should be used for funding scientist-initiated project grants (RO1 grants). This is particularly applicable to the National Cancer Institute which has been spending substantially less on RO1s than have the other institutes.

2. Greater stability of support of biomedical research is urgently needed. This would require that the National Institutes of Health consider more carefully the effect funding in one year has on the commitment base in the next two or more years. Consideration should be given to funding more grants for periods longer than three years; providing other forms of institutional funding like the Biomedical Research Support Grant; reinstituting career awards; and increasing the number of career development awards. Multi-year planning for research support can of itself, in principle, help in reducing instability.

3. The peer review system is vital to a strong research effort and the efficiency of its operation should be diligently nurtured. Adequate peer review should apply to all National Institutes of Health awards.

4. A continued supply of highly qualified scientists for the biomedical research enterprise must be worked into a multi-year plan.

Respectfully submitted,

Mahlon B. Hoagland, M.D.

*List of Delegates attached

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DR. FEDERICO WELSCH
October 3, 1978

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STATEMENT FROM AIRI TO NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES. PANELS ON FUNDAMENTAL RESEARCH AND ON UNIFYING CONCEPTS.

The following recommendations on Health Research Principles were unanimously approved at the Annual Meeting of the Association of Independent Research Institutes on September 15, 1978.

1. Greater STABILITY of support of biomedical research is urgently needed, i.e., NIH should consider to (a) fund more grants for periods longer than three years and so inform study section membership (b) reinstitute career awards for outstanding Scientists and increase the number of career development awards (c) seek an increase in BRSG funds (d) carefully consider the effect funding in one year has on the commitment base for the next or more years (i.e., additional equipment funded with FY 1979 funds would not increase the commitment base for future years).

2. A substantially greater proportion of NIH funds should be used for funding scientist-initiated project grants (RO1s). This is particularly applicable to NCI, NIEHS and NIDR. Most other institutes spend at least 60% of their appropriation for this purpose.

3. The peer review system is vital to a strong effort and its operation should be made as effective as possible. ADEQUATE peer review should apply to ALL NIH awards.

4. A continued supply of highly qualified and trained scientists for the biomedical research enterprise must be worked into the multi-year plan.

I would like to add that we would like to see NIH pay particular attention to how the FY 1979 funds will be distributed. The possibility of funding applications to a priority of 250 during FY 1979 raises the specter of not being able to fund much higher priority grants during FY 1980. The referral office at NIH should be encouraged to more frequently make dual or triple assignments so that applications funded by the different Institutes are of similar high quality and do not differ substantially in their priority rating.

Our insistance in allocating a larger proportion of the NIH appropriation to ROls is that this is the most economical way to fund high quality basic (and also applied) research. It focuses on high quality and does justice to basic or fundamental research. It does not call fundamental any research not included in the clinical trial index as the newly coined "Science base" term does.

The comments just made should also be extended to ADAMHA.

Sincerely yours,

Federico Welsch, M.D., Ph.D.
Governmental Affairs Liaison

FW:mc

cc: Dr. Lewis Coriell, President
Dr. Mahlon Hoagland, Past President
Dr. Herbert Hauptman, Vice President

Richard L. Pharo, Sc.D. Eye Research Institute
Assistant to the President for Science Boston, Massachusetts

I am here to share with this panel the experiences gained at my own Institution, and observations of other similar institutions regarding the need for maintaining a balance of adequately funded basic research if biomedicine in this country is to continue to advance against disease.

In that past several months, much has been said and written on the subject of the maintenance of a proper balance between basic and applied research. Part of the difficulty in addressing this question has been the problem of defining basic research. Definitions have ranged everywhere from basic research being only theoretical, cognitive studies, to basic research being what I do and applied research being what you do.

The current working definition of basic research as being investigator-initiated research, while fraught with pitfalls, is perhaps the most vaild yet proposed. An individual who conceives of a hypothesis applicable to a given biological situation, and details the method of testing it, is most likely dealing with a basic concept or principle. A proposal prepared by a group or an institution, while perhaps containing some basic research, generally involves a multidiscipline application of proven hypotheses to a clinical situation.

Because of the personal and individual nature of health care, there is no major integrated health care delivery industry in this country comparable to the industrial complexes in other areas of the economy. Therefore, the federal government has assumed the responsibility of providing the overall coordination of these matters through licensing and regulations. The government has also assumed the responsibility for providing for the conduct of research in this area. Thus, because applied research can only follow from basic research, the federal government must provide for basic research as well.

The course of basic research cannot be predicted with any certainty. Therefore, it is difficult to make projections about where basic research should go. General areas of biomedicine can be designated in which basic research should be conducted. However, sufficient opportunity must be maintained for an investigator to pursue a truly innovative line of research if he or she can demonstrate that it is scientifically valid. Experience shows that the majority of investigator-initiated research programs fall within the parameters of specific priorities of funding agencies. Care must be taken not to deny *a priori* proposals outside of the priorities.

Along the same line, consideration should not be limited against proposals from disciplines outside of the standard biology disciplines. As experimentation proceeds on smaller, more basic aspects of a problem, the world of the bios begins to meld with the world of the non-living. Information processing theories, materials sciences, electronic theory, engineering, etc. impinge more and more on biological understanding. Room for emphasis must also be provided for research in the medically-related sciences such as epidemiology, biostatistics, sociological medicine, and basic rehabilitation.

Two major areas of federal policy which impact on basic research must be monitored. The first deals with stability of funding. Notwithstanding the denials of agency staff members, it has become a practice of late to shorten the period of support provided for a research project. This shortening has resulted in large part from a general policy that has filtered down through the bureaucracy from higher offices to those whose responsibilitiy it is to make such determination about project length. The influence, though subtle, has been there. Investigators are being required to spend 10-15% of their professional time in merely preparing proposals for continued support of their research. Accountability is indeed important, and must be continued. However, the uncertainty of support for an investigator's project makes it difficult for him or her to develop a stable working staff, and develop the strong momentum that makes for a successful research effort. Basic research support must take into consideration stable research support.

The second area concerns training of new professionals to come into the field. Again, government policies in recent times have sought to reduce the input of scientists into basic research. We are all aware of the invaluable influence that young investigators have on the course of research. They tend to approach a problem with a freshness and with a lack of preconceived inhibitions. This input, although lacking in experience, is the leavening that propels research along. Basic research must continue to have this vital force if it is to continue to provide that basic foundation of knowledge upon which all other research rests. A principle of fundamental research must include this most important aspect.

William R. Barclay, M.D.
American Medical Association
Panel I
Fundamental Research

Support of Basic Biomedical Research

The knowledge and technology applied in providing medical care and in preventing disease are generally based on discoveries of a fundamental nature, which may at some time appear to have demonstrated little relevance to health care. Frequently several pieces of fundamental research disparate in time and topic become drawn together to produce a completely new insight into a disease process or to form a powerful new tool for use in medicine.

If medical science is to continue to advance in scope and excellence as it has done in the last 30 years, then basic research must continue to have the support of government funding. Although some basic research is funded by and conducted in industry, academic institutions have been the principal site of basic research. There, studies have been funded primarily by government.

The acquisition of new knowledge is a painfully slow process and generally occurs in small increments and is not always unidirectional. An investigator may spend a large effort to elucidate what appears to be a relatively minor appearing phenomenon. This may then call into question some well accepted paradigms and call for re-examination of earlier studies. Finally, when the new theory has been examined by others, the older theories put to rest and a new paridigm accepted, the original investigator's research project becomes viewed in a totally different light than when it was first proposed or undertaken.

The National Institutes of Health of the United States have been a major source of support for and a major contributor to new knowledge. Much of the fundamental work that has led to the remarkable medical advances of the last 30 years came about through the extramural and the intramural NIH programs. The peer review system that has been used by the NIH has proven to be sound in assuring high quality of research while at the same time protecting the privacy of investigators' ideas. Furthermore, the NIH has funded project research grants without imposing controls and regulations that might have stifled innovation. An investigator who proposed a study which was approved and funded was generally assured continuing research support for at least three years and could change the direction of the investigation, when circumstances dictated, without compromising that support. The level of funding available to the NIH was for many years sufficient to assure continued support of promising lines of investigation without unduly restricting the granting of new awards.

The encouragement of young investigators and the initiation of new research projects are matters of the gravest concern. Currently the number of new approved grant requests that can be funded through the NIH is falling steadily. This is due to the high cost of present day research, the number of grants that should be renewed and the competition from contract research and field trials, which are totally different in form and philosophy from basic research. Furthermore, the voluntary health associations that could at one time fund much new basic research are having financial problems and now can give a smaller part of their funds for such research.

We need a declared national policy on medical research that will place basic, fundamental studies in an equitable relationship with other health expenditures. The proper government advocate on behalf of basic research is the NIH. Government funding of basic research should be predominantly through the NIH although some support will obviously continue to come through other agencies of government such as the Department of Defense, the National Space Agency and the National Academy of Sciences. Funding of basic research should be predictable for more than one year. The budgeting process should make clear what sums will be available for new competing grants, in addition to the funds being allocated to support ongoing projects.

Although the support of research for certain specific areas in medicine has been legislated, this is not the most efficient or desirable way to encourage basic research. Some scientists feel that through such a process some institutes have received inappropriate funding when measured against the support given to other institutes. The Director of NIH, with advice from NIH staff and advisory councils, should recommend the allocations of resources between the various institutes and programs and not be constrained by the specific pieces of legislation that favor one disease or approach over all others.

The AMA has had a long and sustained interest in the encouragement of basic research. The Advisory Committee on Medical Science to the AMA Board of Trustees made a report in July, 1974 on support of biomedical research that was accepted by the House of Delegates and constitutes the Association's official position on this subject. A copy of that report is appended to this testimony.

Attachment

NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

October 3, 1978

Fundamental Research -- Unifying Principles

Ernst Knobil, President-Elect

The American Physiological Society

In its 1976 report, the President's Biomedical Research Panel reaffirmed the widely and tenaciously held view that fundamental, or basic research in the biomedical sciences, including behavior, yields ". . .The science base upon which to build improved technologies for the prevention and cure of disease." It went on to say that: "Before there can be intelligently conducted applied research, before there can be demonstrations or clinical trials, or before there can be public dissemination of techniques, there must be enough productive basic research to provide the fundamental science from which these efforts flow".

It appears that the current administration shares this view but it reminds us, with increasing frequency, that the resources which have been available to support the nation's biomedical research efforts are unlikely to expand. It is even probable that they will decline as an aftermath of Proposition 13.

Basic research is a quest for new knowledge and understanding, an exploration of the unknown wherever it may lead. In the words of Secretary Califano: "There must be freedom to pursue research topics that are not immediately relevant, for basic research is nothing less than a long-term investment and one cannot program or order neatly the mysterious and serendipitous ways in which new knowledge is developed"(1). I must recall at this point that new knowledge and understanding is the sine qua non of all significant advances in the conquest of disease and the maintainence of health.

If the discovery of new knowledge and the acquisition of new insights cannot be preprogrammed or directed and if their application or relevance to the solution of urgent health problems cannot be predicted, how then can limited resources be rationally allocated to support basic research? I believe that such an allocation must be mandated on some formula basis lest the goose that lays the golden egg be consumed by the claims of more immediate and undeniable needs.

By recent accounting 28% of the total NIH R & D budget has been allocated to basic research, down from 38% in the mid-1960's (2). I suggest that a proportion of this magnitude, say no less than 40% of all funds appropriated or assigned to categorical institutes, divisions, commissions and programs, be automatically obligated for the funding of basic research. A form of basic research overhead, if you will.

Because the only predictable outcome of a basic research effort is that it will come to naught unless it is pursued by good scientists, I further propose that this basic research overhead be pooled and allocated to investigator-initiated research projects solely on the basis of scientific merit as judged by peer review.

Such a mechanism will ensure, over time, the construction of a suitable science base for application to specific health problems, will depoliticize the funding of basic research and provide continuity and stability of support in the face of changing passions in the health arena, an absolute requirement for the viability of the scientific enterprise.

(1) Address to Annual Meeting of the American Federation for Clinical Research, San Francisco, April 28, 1978.

(2) Basic Research in the Mission Agencies. Report of the National Science Board, National Science Foundation, 1978.

E.L. Pratt, M.D., Fundamental Research
Director, Cincinnati Children's Hospital Research Foundation
(Presented by John C. Partin, M.D., Program Director, The Clinical Research Center, Children's Hospital Research Foundation)

PANEL I: FUNDAMENTAL RESEARCH

We need more advocates for children. Many more influential adults should be working for a just share of support for our children, including a just share of support for basic biomedical research in children's diseases. Socrates (469-399 B.C.) exhorted, "What mean ye, fellow citizens, that ye turn every stone to scrape wealth together, and take so little care of your children, to whom ye must one day relinquish all?" No state can affort the enormous financial burden of caring for deformed, apathetic, stunted children who then become inadequate, unfulfilled adults, dissatisfied with Society.

Infants, children and adolescents constitute over one-third of the population. Only by preventing deaths or disabilities in these age groups can one preserve all the working years, the tax paying years, and homemaking years to the benefit of themselves, to their families, and to Society.

Basic research into pediatric diseases provides the greatest cost effectiveness of any health measure. The consequence of birth defects, including markedly low birth weight, is the loss of 80 billion dollars each year in income, as well as the proportionate number of dollars lost from taxes on that income. The cost to the nation of specific diseases is a function of not only the number of cases, but also the duration of the disability influencing the wages lost and the expenses of care for the individual. Several cost analyses by Fudenberg, Stickle, McCory, and others have shown that death and disability in childhood cause a far greater number of life years lost and earnings lost than the corresponding losses from heart disease, cancer, and stroke combined.

Thus, for both humanitarian and national economic reasons, all of us should advocate more support to discover new biomedical information about unconquered pediatric disorders in order to: eliminate or prevent illnesses; devise treatments for currently untreatable diseases; improve and simplify available management for patients. As children thrive, so mankind may thrive.

A second need is to influence the decision makers in Congress and in HEW to appreciate the far greater benefit derived from basic, unrestricted research as opposed to applied, targeted studies directed toward a specific objective. This requires a comprehensive understanding of how medical research is conducted.

Basic research is a persistent effort to make an original discovery. That is, to uncover something previously unknown. By definition, if the findings are truly new, they are unknown in advance. Basic research is a group of gambles, only a percentage of which succeed, often in unexpected directions. Basic research searches for new knowledge of the subject rather than emphasizing any immediate practical application thereof.

New discoveries are commonly at variance with accepted ideas and thus, at firs may be rejected even by the scientific community, and often are deemed to be frivolous, wasteful exercises by those controlling research monies.

Applied, directed or targeted research is carried out to find a narrow, specific, practical application of the knowledge derived previously from basic research. Applied and contract research are attractive to granting agencies because they like to know that they are going to get what they are paying for. However, without the stockpile of discoveries from previous basic research, targeted research and contracts cannot go forward.

It is incumbent on those responsible for the nation's well-being to bolster support for basic research. Renowned scientists, from Karl Compton and Vannevar Bush in the 1930's to Kornberg, Comroe and Dripps in 1976, have examined how scientific advances are generated. All demonstrated the value of and greater payoff from basic research. The analysis of how clinical advances in ten major cardiopulmonary diseases arose showed that two-thirds of the key contributions were derived from basic research done in universities and research institutes.

Many individuals have a confused, distorted image of what science can accomplish as a result of the "Manhattan Project" and the Man-on-the-Moon "Space Program". It is not appreciated that both of these were directed, applied research efforts that succeeded only because basic research already had produced the fundamental knowledge essential for them. This knowledge came from scientists doing basic studies in laboratories in many parts of the world over scores of years. These basic endeavors had not been supported by the Manhattan nor Space Programs.

The scientific discipline of basic research, to discover something new, is to examine sharply defined phenomena by asking small, discrete questions to which the research can provide an answer, albeit just what the answer will be is unknown ahead of time. Most of these forays into the unknown in biology and medicine can be done relatively inexpensively.

The most effective mechanism of support is to provide proven university departments and successful research foundations with sufficient funds to allow their established scientists or promising young research trainees to carry out pilot experiments or to followup new leads that have arisen during the course of other investigations. Then, these preliminary observations can be formulated into basic research grant proposals to be funded via a competitive peer review system, if the system is oriented toward basic research. Such a system will inevitably increase discoveries upon which applied research has to be built.

Currently the Government does not like to spend money for research unless it knows in advance what it is buying. Programming support for research to exclude uncertainty of results produces merely more details about what is already known. The most sensible approach is to move a larger proportion of the current biomedical research dollars into support of preliminary, pilot studies and also into more emphasis on basic investigations. We should be willing to accept more risk by furnishing more "venture capital" to provide the new knowledge that will improve the quality of life for our citizens.

What is needed is more funds distributed into the combination of Biomedical Research Support Grants (slated to be eliminated by the budget reductions for fiscal 1979) and grants for basic as opposed to applied research and contracts.

An additional critical area is the support for trainees in research. Highly relevant to this subject is the sociological review in 1967 pointing out that out of the fifty-five American Nobel Laureates, thirty-four worked as young men under a total of forty-six Nobel Prize winners. A study at our College of Medicine likewise shows that investigators with a background of research training are more than three times as apt to make important biomedical contributions than those without specific research training. To move forward in the future, it is evident that young people must be trained now in basic research skills.

Some current trends in the funding of research are appallingly destructive to basic biomedical research. One is the unacceptability of proposals that suggest going out into the unknown in order to understand the essence of the biological system, with no preconceived bias as to what the results will be. Such proposals cannot meet the NIH Guidelines for Grant Proposals, "furnish details of data expected to be obtained..."

Second is the increasingly large amount of NIH grant funds being channeled into directed, targeted research. Well meaning lay groups and legislators clamor for solutions of disease problems that they consider of prime importance. Directed research programs against cancer, aging, sickle cell disease, mental retardation, perinatal diabetes, stroke, and many other problems now get preferential treatment by the grant system. Huge sums are allocated to these projects. Some good research has resulted from these directed projects, but much money and talent is wasted because the time is not ripe and basic information is not available for solutions to these complex, multi-etiologic, poorly understood disorders. Funding of these special programs, with their large administrative bureaucracy, leaves little money for research project grants.

Investigators who depend upon outside funding turn to programs supported by directed research. Many scientists with experience and expertise in some basic research area are forced into anomalous subjects dictated by interest groups unfamiliar with the ways of biomedical research and medical programs.

The uncertainties of support, with higher and higher proportions of "approved but not funded" grant requests, means that highly capable scientists are being kept out of the laboratories more and more to write grant applications, renewal requests and multiple progress reports. The time spent per investigator on these non-research activities has increased manyfold during the last ten years, to the detriment of new discoveries through basic, unfettered research. William Cooper Procter's investment in the Children's Hospital Research Foundation has made it possible for many more children to be healthy here in Cincinnati, in the U.S.A., and throughout the whole world, than, if instead, he had devoted the same number of dollars to the care of children in community clinics and as patients in hospitals.

American Society of Biological Chemists

Comments with Respect to the National Conference on Health Research Principles (to be held at NIH, October. 3-4, 1978)

1. The allocation of resources to fundamental research and among fields of fundamental research.

This subject, although conceded to be of great importance, is frequently dismissed as unapproachable. Progress in basic science remains shrouded in a mystique of ill-defined concepts involving creativity and serendipity. Clearly the unknown cannot, a priori, be charted. But it seems reasonable to suggest that within the extensive biomedical research experience of the past 25 years, there lies available for analysis, evidence bearing on the likelihood of progress within a particular field, over a certain period of time, given the initial state of knowledge, the number of available researchers, the state of some allied fields, and the nature of the barriers to progress.

It is plausible to suggest that the mystique of serendipity is an anachronism derived from the stochastic nature of scientific progress in a time of few researchers and very limited resources. Scientific discoveries--even those regarded as major--seldom, if ever, require a large advance or change in thought. Given the state of a science and the availability of certain techniques and research approaches, such advances would most likely be made soon by a second person, were they not made by the first.

Thoughtful analyses of some carefully chosen fields of research over the past twenty-five years might yield valuable insight as to an "efficient" allotment of resources to a given field dependent upon certain parameters pertinent to the field. It seems time to begin a pragmatic sociology and economics of scientific research.

2. The priority of basic research.

That "our ability to cope with disease" varies directly with our understanding of disease "is an ultimate truth but not necessarily a proximate truth. Patently disease can be reduced by its prevention or by restriction of its spread; neither process need require profound understanding of the disease. It is debatable whether the alternative approaches have received adequate attention.

3. The longer-range objectives of biomedical research.

The initial objectives of medicine were unequivocal: to ameliorate or eliminate the effects of biological foes upon human welfare. We have gone beyond such objectives to challenge the "defects" bequeathed to us by our inheritance or acquired by sub-optimal choices in the course of life. These newer goals pose largely unanalyzed questions as to the nature of a "defect", the virtue of planned genetic modification, the ultimate social objective of research on the aging process, the rationale for the allocation of ultimately scarce, complex medical procedures, etc., etc. In the euphoria of technological possibility, social desirability is often ignored--possibly to our cost.

Robert L. Sinsheimer
Chancellor

PRESENTATION TO THE NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES
ON
FUNDAMENTAL RESEARCH

Testimony of Charles L. Christian, M.D., Physician-in-Chief, Hospital for Special Surgery, New York City; Member, House of Delegates of the Arthritis Foundation; Past-President of the American Rheumatism Association Section of the Arthritis Foundation; Member of the National Arthritis Advisory Board.

The National Center for Health Statistics will soon be reporting in its 1976 survey that arthritis prevalency in this country has apparently increased by 30% since 1969 and that disability resulting from arthritis has risen by almost 50% between 1967 and 1976 -- from 3.5 million to 5.3 million. Continued neglect of the arthritis research field will inevitably impact upon the ability of the medical community to deal with the increasing numbers of persons afflicted with arthritis who are threatened with disability and will have an adverse cumulative affect upon a large segment -- some 12% -- of this nation's population.

The National Arthritis Advisory Board is extremely concerned that while Arthritis Centers have received some funding -- $2.5 million in 1977 and $5.2 million in 1978 -- the capacity of NIAMDD to provide new research opportunities has decreased since 1976. The 1977 research budget for arthritis was only saved from complete disaster by a Supplemental Appropriation which enabled arthritis research to increase by 2% over 1976 in terms of dollars, but which resulted in a decrease in actual number of new grants funded and a decline of 33% in the ratio of grants funded to approved grants.

In FY 1977, NIAMDD reviewed 143 competing research grant applications in arthritis, of which, 115 were approved but only 35 funded. In 1978, research funds have increased only 6% over 1977, thereby exacerbating this already critical situation. In any year, such a low percentage of approved grants being funded would be regarded as disastrous, but in the case of arthritis it is particularly disheartening because of the vast opportunities presented by arthritis research at this particular time.

It has been recently established that several major forms of arthritis, including Rheumatoid Arthritis and Ankylosing Spondylitis, are influenced by genetic factors. These illnesses provide a unique opportunity to characterize the role the histocompatibility antigens have in increasing susceptibility to arthritis and also to identify the causative factors. Once this is known, methods need to be perfected for detecting the genetic marker so that high-risk persons can be identified.

Studies then need to be designed to characterize Rheumatoid Arthritis and other inflammatory types of arthritis in regard to the presence or absence of the marker, the severity of the disease, how the disease progresses, etc. These studies will only be of value if they can be carried out on a sufficiently large scale to permit significant subgrouping. This means a large number of patients and investigators in 10-20 arthritis centers. The studies could have a major impact on diagnosis and treatment of the disease.

A concentrated effort should also be made in immunology in which new leads could benefit cancer victims as well. Sophisticated laboratory methods now make it possible to identify and characterize antigens involved in the body's immune process. The identification of antigens involved in the mediation of immunologically induced inflammation in Rheumatoid Arthritis and Systemic Lupus Erythematosus (SLE) could be the missing link in determining the cause of these two major types of arthritis.

More powerful but targeted drugs need to be developed. Immunosuppressives used in cancer chemotherapy are commonly avoided in arthritis treatment because of the side effects which render the patient susceptible to many lethal ills. What is needed is an immunosuppressive drug capable of being targeted directly at the specific immune responses that mediate arthritis. While not a cure, such a drug could successfully control rheumatoid arthritis.

Special attention should also be given to the effects of viruses that infect lymphoid cells. These viruses are known to play a major role in Rheumatoid Arthritis and SLE -- inflammation of the blood vessels in both diseases and inflammation of the kidneys in the latter are both induced by deposits of immune complexes. The potential exists for altering, preventing or even solubilizing such deposits. Additional knowledge is needed as to what causes these deposits.

The research area of inflammation also holds promise for several diseases other than arthritis, including cancer and a variety of infectious diseases, as well as for avoiding rejection of transplanted organs. The means for interrupting inflammation at one or more stages has not been developed. This is because the precise molecular mechanisms which activate and feed the inflammatory process are unknown. Although this knowledge will not necessarily produce information on the causes of arthritis, much more effective treatment of inflammatory arthritis would result.

In regard to osteoarthritis, the principal new direction should be chemical studies of collagen and the interrelation of collagen and connective tissue. The immediate goal is to determine how each type of connective tissue is formed and how this formative process is altered by disease, including the chemical response to disease. This is the first step toward some type of chemotherapy to interdict the chemical change experienced in the affected joints of osteoarthritis victims.

A final major area of investigation which could eventually benefit arthritis victims is the study of regeneration of tissue in amphibians which should be translatable to mammals, i.e., how are damaged tissue components removed, what stimulates this activity, and how is cellular growth accelerated and regulated.

Arthritis research findings are of fundamental significance to many of the major plagues of mankind including cancer. During the past 20 years, arthritis research laboratories have defined many of the basic concepts in immunochemistry, immunobiology, and immunogenetics as well as metabolic regulation and the structure of molecules making up the connective tissues.

Many of the world's laboratories that are considered foremost in current research at a fundamental level in cancer, heart disease, gastrointestinal disease, and nervous system diseases, had their starts from research groups which were initially devoted primarily to the study of rheumatic diseases. This is because of the interesting relationship between the rheumatic diseases, autoimmunity, and fundamental immunology.

In a similar fashion, fundamental investigations in the area of connective tissue have been based in arthritis disease research units because of the early concept that arthritis was a connective tissue disease abnormality. Such efforts have given rise to an understanding of genetic defects, structural molecules, and better information for understanding the structure of blood vessels, bone and other components. The far-reaching impact of this research, which is progressing so rapidly in many areas, cannot be overestimated.

It is for these reasons, and not for the sake of identifying a categorical approach to medicine, that a major increase in arthritis research at this time is so important for it likely will continue to influence research in many other disciplines.

PRESENTER'S NAME: John A. Wacker
INSTITUTION AFFILIATION: Association for Children with Learning Disabilities
PANEL ADDRESSED: Fundamental Research

A list of "Areas of Research Needed in Learning/Behavioral Disorders" is included in the attachments. One of the least researched areas but one which the public is coming more and more to realize is extremely important is the effect of nutrition and human ecology on behavior and learning. But, as you will note, many more areas of research are indicated.

Last March NINCDS joined with ACLD in sponsoring a neurological research workshop. Ace researchers from many different areas of the fundamental neurosciences were brought together to discuss their work. By concensus they developed a list of projects considered basic to understanding brain function and learning dysfunctions. At the top of the list of the 20 research projects considered by the researchers to be the highest priority was the need for researching long-term effect of use of drugs in children. Parents of learning disabled children have historically been very willing to cooperate in research that could help their children. We estimate that in a major research effort at least 20,000 learning disabled children would be available for certain types of research.

Eleanor Seiling, President
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PANEL 1 - FUNDAMENTAL RESEARCH

Fundamental research, that is, basic research, has received substantial support from the Federal Government since at least 1937 when the National Cancer Institute was established. In 1977, Federal obligations for basic research were projected at $2.5 billion. (From: "Federal funds for research, development, and other scientific activities," NSF 77-301, December, 1976). During House Appropriations Hearings on the National Science Foundation for FY 1979 (Pt. 5), Dr. Richard C. Atkinson, Director, NSF, stated that federal budget increases for the NSF and other agencies "reflect the awareness of the President and his advisers that basic research develops the fundamental new knowledge needed for advances in such areas of national need as health, energy, environmental and the economy."

Support for basic research continues to increase despite the fact that there is virtually no consensus as to its meaning. During House Appropriations Hearings on the NSF for FY 1978 (Pt. 1), Rep. Traxler questioned Dr. Atkinson, Director, NSF, about the meaning of basic research: "Dr. Atkinson, on page 139 of last year's hearings, Dr. Creutz said it's sometimes difficult to define what one means by basic research. Part of the difficulty our committee has and I am sure other interested committees in the Congress have is if we can't define basic research how is it that we can devise intelligent budgets which promote basic research."

During Senate Appropriations Hearings on the National Institutes of Health for FY 1979 (Pt. 2), Dr. Donald S. Fredrickson, Director, NIH, stated: "I want to stress, Mr. Chairman, that so-called basic research... is a very difficult term to define. No two scientists, no two people, will agree on exactly what is applied or what is basic among the activities which

NIH supports." He went on to say that basic research means "different things to different people and at different times," and that this frequently causes difficulty in classifying what type of research federal dollars support. He added: "The experiments confirm the inescapable subjective nature of such a classification [i.e. applied vs basic] ...." (underline supplied).

Our elected officials also have difficulty defining and justifying basic research. In comments inserted into the Congressional Record of September 12, 1978, Rep. Pattison stated that "basic research can often be difficult to explain to our constituents. It is difficult because many research projects seem, at first glance, to be ridiculous. Often there appears to be no connection between a specific subject of inquiry and any useful result." Our research shows that a vast amount of basic research is not only "ridiculous at first glance," but is unspeakably cruel to animals - the electric shockings, the forced animal fighting, the sexual manipulations, the "voodoo" (learned helplessness experiments), the crowding, isolation, and fear experiments, lethal irradiations, and more. Many of these experiments are repeated in laboratories across the country year after year. Students can even earn their Masters and Ph.D.'s by doing these experiments.

During House Appropriations Hearings on the NSF for FY 1979, Dr. Norman Hackerman, Chairman, National Science Board, commented in regard to basic research in industry: "... there has to be support for the kind of basic research which is not directly related to any of the industrial missions or federal agency missions, the research in the area of what I have always called pure ignorance." (underline supplied). (1979 House Appropriations Hearings, Subcommittee on HUD - Independent Agencies). There would not appear to be any valid reason why there should be "pure ignorance" in biomedical research, since it's been going on since long before the birth of Christ, but I agree that "pure ignorance" appropriately describes the animal experiments cited above.

The term "basic" or "fundamental" research has been perverted to mean bizarre experiments on animals in the biomedical and health-related fields. The ambiguity of the term "basic" serves as justification for performing experiments on animals which result in the extremes of no-goal suffering.

United Action for Animals is not opposed to bona fide basic research. In fact, we like to think that we ourselves conduct bona fide basic research, although we have a goal. We object to the perversion of "basic" research to mean animal abuse. Basic research should mean the study of the very fundamentals of life and matter, as is done in physics and chemistry. In biology and biomedical studies, the world of the living cell and its microscopic components, including the cell surface, should be the focus of research. "This miniature world holds the key to the major health problems of today." ("Inside the Cell." DHEW Publication No. (NIH) 79-1051). Basic research does not have to mean the continued torture and abuse of animals.

PANEL 2

CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

THE CANDLELIGHTERS

Parents dedicated to the conquest of cancer

September 29, 1978

Grace Powers Monaco
Candlelighters' Foundation

CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

Principle -- To improve the quality of health care, prevent disease and reduce the burden of health care costs, the health care system requires, in addition to new knowledge developed at the fundamental level, the support of applied, problem-oriented health research.

Candlelighters, an organization of parents of children and adolescents with cancer, submits its comments on the Pre-Conference Draft DHEW Research Principles.

The problem shared by our parents and children is not a small one: after accidents, the second leading cause of death in American children is cancer. Moreover, the financial burden born by each family is second only to the distress caused by the disease itself. A study of 70 families with children in treatment for cancer at the University of Kansas Medical Center demonstrated that in addition to medical expenses (usually covered by third party coverage and installment payments), the out of pocket cost for non-medical expenses usually averaged more than 15% of the family budget. For half the families, the figure was over 25%. These non-medical expenses included loss of pay, transportation

123 C Street, S.E., Washington, D.C. 20003

to distant medical facilities, food and lodging while away from home, child care, special clothing and special food.

The diagnosis, evaluation and treatment of children with cancer must be integrated with basic and clinical research designed to determine the causes, pathogenesis and prevention of their disease and specific, safe, simple and totally effective treatment. To deny children with cancer the opportunity to be included in relevant research is to diminish their opportunity for prevention and cure.

Childhood cancer research has proved to be the single most effective model for understanding and treating many forms of cancer. Developments in childhood cancer have been successfully applied to adult cancers. Pediatric cancers pioneered combined modality therapy utilizing surgery, radiotherapy and chemotherapy, various rescue factor approaches, and adjuvant chemotherapy which have effectively arrested or retarded the development of many adult cancers. Dr. Emil J. Freireich of the University of Texas System Cancer Center in Houston has said that drug combinations pioneered in pediatric cancers are now producing remissions in a majority of adults with acute myelogenous leukemia and a "proportion of these patients are being cured. Five years ago if you asked me if we were producing cures, I could only say, 'rarely'." Additional specific examples include the development of and use of antifols in childhood leukemia which led to curative measures in adult cancers, specifically the use of antifols in women with choriocarcinoma; adjuvant chemotherapy in breast cancer to prevent metastases; and, the combination chemotherapy in acute lymphocytic leukemia which is now being used successfully in adult Hodgkins disease, finally the total therapy concept used for childhood ALL is now being used successfully in cooperative study clinical trials involving adult lung cancers.

These applications of the results of research in pediatric and adolescent cancers underscores the importance of preserving, expanding and building upon the research efforts committed to childhood and adolescent cancers.

In view of the shrinking resources allocated to health, it is important to develop a system that produces excellence in research and provides an optimum in application of research for all children/adolescents with cancer at the lowest cost to the families and to society. Observations by parents in a variety of treatment settings suggest that this research effort can be combined cost effectively with treatment through a nationwide consortium approach to health care for children with cancer.

Described in greater detail, this plan would work toward a guarantee that all children with cancer will have ready access to the most expeditious, safe and effective care available as measured by national standards, that all will have responsible primary physician - advocates, that no family will be economically constrained or burdened by the costs of care, that children's cancer research will proceed vigorously, and that physicians and nurses will be educated about children with cancer.

The consortium approach recognizes the three conventionally defined levels of health care:

Primary (Level I) - located in the child's community, and providing home and outpatient/office health supervision with particular regard to growth and development, prevention of infectious disease, treatment of minor infections, liaison with school and community, and family counselling by professional and by peer group. This would be provided by a pediatrician, family practitioner, internist or pediatric oncologist.

Secondary (Level II) - The pediatric cancer care facility, usually connected with a children's hospital located close to the child's community and providing outpatient and inpatient care for the particular disease and its complications. This would include: administering anticancer drugs according to protocol; maintaining treatment records; and managing moderately severe infections, bleeding episodes, anemia, nutritional and metabolic disorders. This would be provided by a pediatric hematologist/oncologist or a pediatrician with additional training or experience in pediatric oncology. Also, this facility should provide access to childlife specialists, psychosocial support by professional or peer group as well as undertaking an education program directed to medical and nursing students, graduate trainees, and practitioners.

Tertiary (Level III) - A regional children's cancer center. This would be accessible to provide confirmation or correction of initial diagnosis, subcategorization and staging, complete evaluation of the child's needs, thorough discussion among team members and with child and family, assignment to protocol study with consent of child and parents, initiation of therapy, conduct of any Phase I experimental treatment, basic and clinical research relevant to children's cancer, and training of oncologists in research and practice. The child and/or his specimens and findings would be periodically sent to the center for reassessment, change in therapy, investigative studies not available at the secondary level and documentation of disease course.

Secondary care persons might provide primary care as well, and tertiary regional centers could provide primary and secondary care also. This would be decided in accordance with the residence of the child, the particular cancer and its treatment, and the wishes of the child and family.

For child and adolescent patients not actively participating in a research program, a comprehensive registry of the data for childhood and adolescent cancer should be established. These patients could thus effectively participate in the research effort by providing data on effectiveness of treatment, toxicity of therapy and long term effects of childhood/adolescent cancer. Further the cancer center and secondary care level should provide strong outreach services to the community physician. It goes without saying that due to the profile of pediatric cancer in this country (17% of all cancers) consortium treatment with its care and cost benefits requires that adequate transportation funds must be provided for those who must travel great distances for treatment.

Finally, Candlelighters is concerned that the results of cancer research be disseminated as promptly and effectively as possible. To this end, the National Institutes of Health or its designates should be responsible for technology transfer with respect to the research it funds.

INTRODUCTION AND CREDENTIALS OF NATIONAL ACADEMY OF CLINICAL BIOCHEMISTRY

Submitted by Dr. W. Stephen Matthews, President

Employing an excellent characterization of the National Academy of Clinical Biochemistry by Past President Dr. George Grannis, the following has been prepared to introduce the Academy to the National Conference on Health Research Principles.

Members of the NACB are, for the most part, doctoral scientists (Ph.D. and/or M.D.) with education and training in analytical chemistry, human biochemistry, and other basic biomedical sciences, five years of post-doctoral experience in the field, and who are Board-certified and practice their specialty in the hospital or academic environment. There are currently approximately 225 members of the Academy, and there are probably fewer than 1,000 scientists in the United States who are eligible for membership. Although, clinical biochemists are small in number, they are an increasingly essential component for the delivery of high quality health care.

Clinical biochemisty is, in part, an applied science that interfaces basic biochemical and physiological research with the analytical technology of the clinical laboratory. The clinical laboratory provides essential services to medical practitioners, who in turn interact directly with the patient. Census figures demonstrate that our population of some 200,000,000 people is served by about 300,000 medical practitioners, who are served by some 13,500 clinical laboratories. These laboratories are staffed by approximately 13,000 medical specialists in pathology, 140,000 medical technologists, of whom 90,000 are certified, and about 3,000 doctoral scientists, of whom about 400 are board-certified clinical chemists. Of the 13,500 clinical laboratories, about 3,000 are independent commerical enterprise, 3,500 are in clinics or government health service facilities, 6,000 are in hospitals having fewer than 350 beds and the remainder are in hospitals having more than 350 beds. Of the latter, perhaps 400 are in academic Environments where basic biochemical research is performed, and where personnel for the health care system are educated and trained.

Clinical laboratories, particularly in the larger academic institutions, are sophisticated enterprises. Many analytical methods are based on advanced analytical principles, using automated, computerized instrumentation. A wide variety of tests are performed whose interpretation requires comprehensive technical and medical knowledge. Because of the complexity, the operation of these laboratories requires the collaboration of both medical and technical specialists. The medical specialists (e.g. pathologist) tend to function at the interface between the practicing physicians and the laboratory, while the technical specialists (e.g. clinical biochemists) tend to interface with basic research and analytical technology and the applications thereof to specific medical problems. These technical specialists, among other things, bring new test procedures into the laboratory, investigate their usefulness in clinical situations, and conduct research on various problems of medical and biochemical interest.

This type of collaborative research involving the clinical laboratory and medical practitioners has value that extends far beyond the research endeavor itself. Such collaborative studies are valuable for the contribution they make to research, service, and education - all of which are primary areas of concern to clinical biochemist.

The point is that the translation of the results are basic biochemical knowledge into practical clinical applications, and the dissemination of these applications to the medical community, is an essential activity and requires continued effort. It has been said that the practice of medicine is perhaps twenty years behind the state of the art simply because most people tend to practice at the level at which they were trained, with modifications as advances are disseminated from the academic centers. It could be documented that clinical biochemists who practice in these hospital situations are essential for the introduction and dissemination of relevant new technology in the clinical laboratory services that are available to the health and medical care system.

STATEMENT ADDRESSED to the PANEL on
CLINICAL APPLICATIONS and HEALTH SERVICES RESEARCH

public testimony for the National Academy of Clinical Biochemistry

Once again capitalizing on the words of Dr. George Grannis, the following statement expresses the view of the Academy on this very important topic.

SUPPORT of CLINICAL BIOCHEMISTRY

(a) Pre-doctoral training of clinical biochemist: In the late 1960's training Grant Programs provided stipends, fees, and incidentals for pre-doctoral trainees in Clinical biochemistry. It has been observed that during the years grant support was available, the ''quality'' of the trainees steadily increased and virtually all participants attained the doctoral degree, many with distinction. These graduates have accepted responsible positions in clinical biochemistry and the majority have become board-certified. The training grants were discontinued in 1976, although in some cases extensions were made to fulfill previous commitments. With the demise of training support, the number and quality of the applicants has decreased noticeably. This was predictable and is a simple matter of economics. When support was available the trainees could be selected on a competitive basis by merit, and the sincerity of their commitment to a career in clinical biochemistry. In the absence of grant support the applications are perforce limited to those who are financially able to commit themselves to a 3-4 year course of study. As a consequence, a number of provisional admissions have evolved, some of whom will probably terminate at the M.S. level. This is a sad underutilization of human resources. Programs have been developed to produce high quality graduates and now, for want of continued support, the programs are being made ineffectual.

(b) Post-doctoral training in clinical biochemistry. Presently there are no government supported programs that are specifically designed for the post-doctoral training of clinical biochemists, although there are programs for training of research scientists. Institutionally supported post-doctoral training programs do exists but are in the minority. Post-doctoral fellows with degrees in analytical or biological chemistry, or related disciplines, are admitted to a structured course of training

WHICH PERMITS THEM TO FUNCTION EFFECTIVELY IN THE CLINICAL LABORATORY. INSTITUTIONS USUALLY ACCEPT ONLY ONE POST-DOCTORAL FELLOW PER YEAR. THE TRAINING OF A POST-DOCTORAL FELLOW IS DIFFERENT FROM THAT OF A PRE-DOCTORAL STUDENT AND THERE ARE PHYSICAL LIMITATIONS TO THE NUMBER OF FELLOWS WHO CAN BE ACCOMMODATED BY A CLINICAL LABORATORY. THIS IS OF SOME IMPORTANCE BECAUSE THE SUGGESTION HAS BEEN MADE THAT THE GOVERNMENT SHOULD SUPPORT POST-DOCTORAL PROGRAMS THAT WOULD PREPARE BASIC RESEARCHERS FOR WORK IN CLINICAL BIOCHEMISTRY.

(c) RESEARCH IN CLINICAL BIOCHEMISTRY: IT HAS BEEN FEARED BY MANY ESTABLISHED CLINICAL BIOCHEMISTS THAT DHEW HAS A LONG HISTORY OF BEING UNRESPONSIVE TO RESEARCH PROPOSALS RELEVANT TO THEIR SPECIALTY. THERE HAS NEVER BEEN A STUDY SECTION ON CLINICAL BIOCHEMISTRY WHERE SUCH PROPOSALS MIGHT BE ASSURED OF PEER REVIEW. JUST AS STUDENTS INTERESTED IN CLINICAL BIOCHEMISTRY ARE DISCOURAGED FROM APPLYING TO TRAINING PROGRAMS BECAUSE OF THE LACK OF TRAINING FUNDS, SO ARE ESTABLISHED CLINICAL BIOCHEMISTS DISCOURAGED FROM APPLYING FOR RESEARCH SUPPORT BECAUSE OF THE ABSENCE OF A STUDY SECTION IN THEIR SPECIALTY AND THE CONSEQUENT UNLIKELIHOOD OF FAVORABLE REVIEW. IT IS EMBARRASSING, THAT IN 1978 OUR KNOWLEDGE OF RATHER FUNDAMENTAL BIOCHEMICAL CHARACTERISTICS OF HUMAN BEINGS IS SO LIMITED. THE BASIC INFORMATION NEEDED SHOULD LONG SINCE HAVE BEEN ACQUIRED. YET THIS GENERAL AREA - CLINICAL LABORATORY DATA ANALYSIS AND UTILIZATION - IS NOT LIKELY TO RECEIVE SUPPORT AS IT APPEARS TO BE RATHER MUNDANE, AND IT'S NOT ''BASIC RESEARCH''.

TO SUMMARIZE THIS SECTION, THE ACADEMY WISHES TO RECOMMEND THE FOLLOWING:

(A) THERE BE STUDY SECTION TO FOSTER RESEARCH AND TRAINING IN CLINICAL BIOCHEMISTRY,

(B) THERE BE ADEQUATE REPRESENTATION OF CLINICAL BIOCHEMISTRY IN EXISTING STUDY SECTIONS,

(C) THERE BE RECOGNITION IN DHEW PROGRAMS OF CLINICAL BIOCHEMISTRY AS A DISTINCT DISCIPLINE, AND OF ITS ESSENTIAL ROLE IN THE HEALTH AND MEDICAL CARE SYSTEM.

What Can Be Done?

Clinical Biochemistry is an essential well-spring for continued practical advances in clinical laboratory science and service. It is urgent that DHEW evaluate this science, its role in the health and medical care system, and the requirements for its effective nurture. The evaluation should consider what are the current and anticipated needs for training and research in this field, how those needs are currently being met, and how DHEW programs can be expanded or re-structured to more effectively meet those needs.

Possible mechanisms of such an evaluation might be:

(a) Establish a separate Study Section on Clinical Biochemistry or, alternatively provide for representation by clinical biochemists on each relevant existing Study Section.

(b) Re-institute pre-doctoral and post-doctoral training programs, at a level to meet the anticipated needs of the field,

(c) Plan a program for goal-oriented research support in the discipline by identifying major problem areas that are amenable to solution.

(d) Initiate a program of general research support whereby clinical laboratory scientists could investigate unusual clinical problems.

In conclusion, it is imperative that these issues merit further consideration, with assurances that the NACB will be most willing to assist in any future deliberations.

Gerald Landsberg, ACSW

This written testimony is made on the behalf of the National Council of Community Mental Health Centers. The National Council has, as its primary purpose, the establishment and maintenance of comprehensive community mental health programs in the United States. It is a membership organization that consists of Federally funded Community Mental Health Centers and other agencies that provide community mental health services. One of the primary interests of the National Council has been in the area of mental health research and program evaluation. It was based upon this interest, that I as Chairman of the Council on Research & Evaluation of the National Council, have been asked to prepare these written statements for your consideration.

The clinical applications of health services research is an area of substantial interest to the National Council. One of the most distressing aspects of the present state of health research, especially in the area of mental health, is that it frequently occurs in a vacuum and comparative little consideration is given to its utilization in direct clinical practice. The translation of important research findings into clinical applications for use by the direct service practionner is an issue that is of vital concern. Based upon the major interests of the National Council in community mental health, the comments and suggestions which are addressed in this testimony are primarily related to that subject. This testimony will consist of providing suggestions in two areas: 1) the process of developing and implementing research projects; and 2) delineation of ideas for specific research projects or activities.

I The Process of Developing and Implementing Research Projects

The developmental processes focus on: the types of research projects sponsored, how they are developed and implemented, and how findings are disseminated and ultimately utilized. The following suggestions are offered to improve the process of developing appropriate mental health research and evaluation projects and to improve the method utilized in disseminating information emerging from these projects.

A. There is an important need to increase coordination between the three branches of the Alcohol, Drug Abuse and Mental Health Administration. At the present time, the three branches — The National Institute of Mental Health, The National Institute for Drug Abuse and The National Institute of Alcohol Abuse and Alcoholism — frequently operate as distinct entities on to themselves in developing research projects. However, functionally, often the problems of drug, alcohol and mental health overlap. It is suggested that there are many areas in which these three organizations can develop cooperative research projects that produce data that are valuable to practionners in all three areas.

B. There is a substantial need to bring mental health into the mainstream of the health care delivery system. In relation to the development of research activities, frequently mental health is isolated from other aspects of health care. Functionally, mental illness is not easily distinguishable and isolated from general health problems. It is suggested that there needs to be increased coordination of research activities between ADAMHA and other health agencies in the Department of Health, Education and Welfare to develop projects and activities that produce information that is relevant to both health and mental health practionners.

C. The development of relevant mental health research and evaluation projects that ultimately will be utilized by practionners must be given a high priority. To obtain this result, it is suggested that increased emphasis needs to be placed upon obtaining the input of mental health practionners, researchers and evaluators in the process of planning and developing these projects.

D. Frequently, the mental health studies which are available have been criticized from two perspectives: 1) having been conducted by universities which are far removed from the "real world" of direct practice or

2) having been implemented by staffs in direct practice facilities (e.g., Community Mental Health Centers) who lack needed research sophistication. To reduce criticism on both of these grounds and to strengthen the development of research that is based upon practice realities, it is suggested that future research development by NIMH and other branches of ADAMHA stress joint research evaluation projects between universities and direct practice agencies.

E. One of the most difficult and frustrating tasks in relation to research and evaluation is that findings or results often are inadequately disseminated. It is suggested that increasingly we need to turn our attention to developing mechanisms for disseminating on a timely basis research and evaluation findings. Attention needs to be focused on developing mechanisms (e.g., A Clearinghouse on CMHC Program Evaluation and Quality Assurance) that would serve to insure that information is rapidly disseminated to on-line professionals.

II Ideas for Specific Research Projects or Activities

A. A major area of concern for mental health programs is demonstrating the impact and effectiveness of direct service programs. Although for some population groups selected measures for assessing treatment outcome have been developed, for two high risk groups — children and older adults — there has been only limited technology developed for easily utilized outcome measures. It is suggested that this be one focus of our attention.

B. One huge question that is asked over and over again in mental health is "How prevelant is mental illness?" Answers to this question have been very difficult to provide. Existing mental health epidemiological studies are either outmoded or too limited in scope to provide substantially useful information. It is recommended that increased support be given for implementing mental health epidemiology studies. It is also suggested that the National Health Survey routinely include mental health questions. This latter development would provide more routine information that is readily available to the field.

C. The area of biochemical research is becoming increasingly important. It is suggested that increased support be given to research to study the biochemical basis of mental illness. As part of this increased emphasis, stress needs to be placed upon how these findings can be used to improve clinical services.

D. Partial hospitalization programs are a comparatively recent development in the field of mental health. At the moment, only limited research has been conducted to examine the effectiveness and impact. Heightened concern for this topic needs to be reflected in our future planning.

E. Cost of mental health services is an important topic of present discussion. It has been underscored by the present debate about the inclusion of mental health programs under National Health Insurance. It is suggested that DHEW sponsor a series of studies to evaluate the cost effectiveness of direct clinical service program. Included in these studies should be an examination of cost effectiveness of Community Mental Health Centers versus other mental health treatment systems.

F. To what degree are health problems a manifestation of mental illness? To what extent do psychosomatic problems of patients impact on the health care delivery systems? These are just two important questions that need our attention and should be the concern of future health and mental health research.

G. A great number of factors affect the utilization and, ultimately, the effectiveness of mental health care services. The role of community support groups and of the family are all essential variables that effect the utilization of services. Substantially more research needs to be done on this topic to enable practionners to employ findings to improve programs.

H. Client satisfaction is an essential variable that effects both the use and effectiveness of mental health services. Yet, there is still substantially more work needed on this subject to provide a clearer picture of the nature of the effect. Without this increased knowledge, we are limited in our abilities to change our methods of providing service to increase their acceptibility to clients and, ultimately, to increase their effectiveness.

I. Self-help groups are a potentially effective resource for serving the mentally ill. This is especially true for those chronic patients with a long history of hospitalization. It is suggested that our attention must be focused on self-help groups and their appropriate places in delivery of health care systems.

J. Often, mental illness is treated differently than physical illness. By comparison, we neglect to examine the natural history of mental illness. It is suggested that we begin to conceptualize and plan for longitudinal studies across various diagnostic categories that examine the natural course of mental illness.

It is our hope that the information provided to this panel will be of value in your deliberations on this important subject.

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ABYSMAL IGNORANCE IN A LAND OF PLENTY

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The title of this paper was purposefully chosen in the hopes that it would have some impact on the way in which Americans adopt innovations in medicine. Of the $162 billion spent on health care up to one billion dollars is spent each year on fundamental research designed to determine how to prevent and cure disease. No one can fault this expenditure by the National Institutes of Health. In the long run it will pay off much better than the testing of new technologies in humans. But the short-term needs are also important. Only a few hundred million are spent by the N.I.H. on clinical trials and only $25 million are proposed for the National Center for Health Services Research of the Office of the Assistant Secretary for Health. The need to spend ten times that amount on applied research is illustrated by the following examples of our abysmal ignorance:

1) In 1970 the University Group Diabetes Program reported that oral hypoglycemic agents are associated with increased mortality from cardiovascular disease in patients with adult onset diabetes.(1) In 1978 the same group reported that insulin therapy had no effect on survival or on the major vascular complications of that form of diabetes.(2) These findings were soundly protested by two groups: those who profited from the sale of the drugs and those whose research had been directed towards how they worked rather than if they worked. But no one either in parallel or since that time has done the kind of adequate, long-term clinical

trials that could have confirmed or denied the conclusions of the UGDP. One of the reasons has presumably been lack of available funds. The UGDP studies cost over $8 million. Yet in the meantime over $100 million per year has been spent on the oral hypoglycemic agents by Americans, and even more has been spent each year for the hospital care of patients with adult onset diabetes.

For a long time it has been known that the need for insulin and oral agents in obese patients could be markedly reduced or eliminated by rigid dieting. Yet no one has undertaken a large-scale controlled trial of such therapy. If it had been shown that weight reduction not only eliminates the need for therapy but also the cardiovascular complications of the disease, it would be much easier to persuade patients to reduce, and there would be a much greater stimulus for finding better ways to help patients lose weight. As is is, no one is convinced that rigid dieting could result in a cure, so, few people really try. Good studies would cost several million dollars a year, and if they were positive would save several hundred millions by allowing the postponement of degenerative diseases. We are ignorant about how best to prevent the complications of diabetes while we are spending $300 million treating patients who have them. Abysmal ignorance in a land of plenty!

2) It is estimated that 100,000 people are now undergoing coronary bypass operations in the United States each year.(3) The only large-scale randomized control trial, a VA study,(4) has suggested that the only indication for the operation at present

is a remediable lesion of the left main coronary artery. Yet that lesion is probably present in no more than 10-15% of those undergoing surgery.(5) Of the remaining 85,000, an unknown number are benefited substantially from the symptomatic standpoint, but there is no evidence that any of them have their lives prolonged. It seems likely that the majority of those operated on with the idea that the operation might prevent death from a myocardial infarction are in no way benefited by surgery.

It has been estimated that each coronary artery operation costs $10-15,000. If we assume that a conservative 40,000 unnecessary operations are performed each year, at a conservative $10,000 each, we are wasting $400 million in health care costs per year. Several more controlled trials similar to the VA study could be performed in the general population for no more than $10-$20 million in toto. The cost benefit of that is obvious. We remain ignorant about which patients should have coronary artery surgery 14 years after the bypass operation was introduced. If we continue for the next 10 years without obtaining that information, we will have wasted $4 billion.

3) In 1976 approximately 50,000 operations were performed for the elective treatment of patients with duodenal ulcer (a conservative estimate). The literature is loaded with articles arguing that one surgical procedure is better, the same as, or worse than another. Although gastrectomy alone is no longer performed, there are vigorous advocates for gastrectomy or antrectomy plus vagotomy, for vagotomy plus pyloroplasty, or gastroenterostomy, or for various highly selective vagotomies, without

a drainage or resection procedure. There seem to be distinct differences in rates of complications of the operation and relapse of the disease.

There have been 14 randomized control trials of the various operations for the elective therapy of duodenal ulcer. Only one group, the VA Cooperative Study,(6) included enough patients to come anywhere near being reasonably sure that they might not be missing a clinically important difference between one or more of the operations. Twelve of the studies were woefully deficient in numbers of patients. Although over 3,000 patients have been entered into randomized control trials of the various operations,(7) it is not clear as yet which one is superior. In part, this is due to ignorance about the proper design of the trials, and in part it is due to the fact that larger numbers are required to determine the best operation over the long run. So, surgeons continue to perform their favorite operation in relative ignorance, and the cost of proper studies would be an order of magnitude less than what is spent every year on routine surgery.

4) There is some reason to think that the antiplatelet effects of aspirin could prevent myocardial infarction in patients with coronary artery disease, but it is not known whether the long-term side effects of this cheap and readily available drug would outweigh the advantages. Five years ago, after an encouraging but inconclusive report from Wales,(8) the Coronary Drug Project investigators placed patients on aspirin or placebo as they came off the various drugs that had been studied as part of that major clinical trial.(9) Halfway through the study, when a clear trend was

developing in favor of the aspirin patients, the support for the collaborating investigators was stopped by the National Heart, Lung, and Blood Institute. It was argued that the question could be better answered by starting a new study of patients with more recent myocardial infarction, and that is now underway. However, the information being obtained from the Coronary Drug Project patients would still have been extremely useful if it had been possible to free up funds to continue the study to its planned conclusion. Five years after the first suggestion that aspirin might postpone thousands of myocardial infarctions per year we remain ignorant about whether or not it is safe for all of the people with coronary artery disease to ingest it on a regular basis. No studies of primary prevention are underway because they would be so expensive. Yet if the drug worked it would save billions by postponing death and disability.

There is another aspect to our continuing ignorance in the face of an anticipated $200 billion annual health care bill. We don't seem to have an effective system for requiring that physicians pay attention to the results of randomized control trials when they are conclusive. The best example of this is the persistence of radiotherapists in treating women who have had a radical mastectomy for carcinoma of the breast. Five randomized control trials have demonstrated such therapy not only does not prolong life but actually may shorten it.(10) The local recurrences that it prevents in one-third of the patients could be treated in that third when they appear, thus saving the other two-thirds from unnecessary, expensive treatment, and damaging X-Rays. Yet routine treatment is still advocated by the majority of radiotherapists writing in the medical literature. It is difficult to find out how many women are being so treated; the estimate is 30% of those who have had a radical mastectomy, or 30,000 each year. Could this be a waste of $30 million a year? Other examples of the lack of impact of randomized control trials on the practice of medicine are the use of stilbesterol to prevent spontaneous abortion in 1 to 2% of pregnant women up until the time it was discovered to result in cancer of the vagina of female offspring; continued use of bedrest in the treatment of hepatitis; the belief that bland or sippy diets are necessary to treat peptic ulcers in spite of the fact that all randomized control trials have been negative.(11) Small doses of heparin have been shown in a number of trials to prevent postoperative thrombosis and embolism more commonly than they cause serious hemorrhage.(12) Yet the drug is rarely used prophylactically. In these cases the problem results from spending insufficient time and money on the transmission of information.

The same lack of the application of the scientific method occurs in the early development of new diagnostic procedures. For instance, there would not now be the extensive arguments about whether or not enormous amounts of money are being wasted on CAT scanners if patients had been randomly assigned to diagnostic workups with and without the instruments from their first introduction. That could have been done when the instruments were scarce. It is probably too late now.

There are a number of reasons why insufficient funds have been spent on definitive clinical trials in the last 10 to 20 years. Some physicians have been reluctant to admit their ignorance and to subject popular therapies to adequate testing. Others have thought it was more ethical to try innovations in successive numbers of patients, thus making it harder to undertake properly designed trials. Rigid requirements for a peer review of protocols and elaborate informed consent procedures discourage physicians from designing and executing randomized control trials. Some prefer to innovate in the ordinary practice of medicine and thus avoid the red tape or legal responsibility of conducting formal research without proper review procedures. But these objections could be overcome by making sufficient funds available to support such trials. The availability of useful answers would save those costs many times over. We are abysmally ignorant about how best to spend the $200 billion that soon will be spent to keep Americans well.

The National Institutes of Health should not reduce their expenditures on basic research to expand their support of clinical trials. However, if those responsible for the expenditure of $75 billion per year by federal, state and local governments on health care recognized that 5% might be saved if more money were spent on research, the annual savings would more than pay for the research. If some money from other agencies were assigned to research and development, it would not be necessary to develop a new expertise in each agency to disperse the funds properly. The National Institutes of Health have that expertise and could do the job at minimal relative expense.

There remains the problem of how to deal with new and expensive therapies that have not been established as efficacious and safe. In 1962 the Kefauver amendments to the Food and Drug Act required that the FDA establish the efficacy of all drugs marketed at that time. Committees of clinicians and clinical investigators were appointed by the National Research Council of the National Academy of Sciences to classify "old" drugs as efficacious, doubtful or ineffective. The first were then approved for continued use and the last withdrawn from the market. Marketers of the middle group were given one to two years to establish their efficacy or withdraw them from the market.

Non-pharmaceutical therapeutic maneuvers should be subject to the same review process, as the FDA is presumably doing for expensive gadgets. The marketers of unestablished treatments, in this case physicians and surgeons, should be prohibited by hospital peer review committees from using them until they have established their safety and efficacy by well designed clinical trials. Just as federal support of research was an effective leverage in requiring peer review and informed consent in the case of all clinical research, so also the threat of withdrawing federal funds from hospitals that allow money to be wasted on unproven diagnostic and therapeutic measures would bring about the adoption of proper procedures in the control of innovation and the unwarranted use of outmoded treatments. Requiring physicians to justify their exploration of unproven therapies would not stifle medical care, as will be charged. Instead it will reduce or eliminate the gap between good clinical research and bad practice, to the benefit of the patient.

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Introduction:

The Association for Research in Otolaryngology (ARO) membership consists of basic and applied researchers who dedicate their efforts to fundamental or clinical problems related to otolaryngology. Membership in the American Council of Otolaryngology (ACO) is opened to all board qualified otolaryngologists. It should be stressed that otolaryngologists work with and draw upon expertise from many related professions and scientific disciplines (audiology; psychophysics; special sensory system physiology; systems control and electrical engineering; immunology; biophysics, speech sciences; communication theorists, dental medicine and psychology to name only a few).

Otolaryngology (otorhinolaryngology) is the specialty of medicine and surgery which diagnoses and treats patients with afflictions of the head and neck. In some cases, such as head and neck cancer, the fundamental problems, except for the complex anatomy and physiology, are similar to cancer occurring elsewhere in the body. In other instances, the patient presenting to the otolaryngologist may have problems which require singular expertise i.e. the special senses (auditory, vestibular, olfaction and taste).

The prevalance of most ENT diseases and disorders is unknown, however surveys conducted in the past have indicated that 25 to 40% of the primary patient complaints received by family practioners pertain to the ear, nose or throat and comprise the single largest category of presenting complaints.

Present Status:

For ear, nose and throat problems which overlap with other medical specialities, advances in otolaryngologic care have kept pace with those in other medical specialties and often otolaryngologists have led the way. On the contrary, advances in the physiology and pathophysiology of special sensory diseases have lagged behind other fields of medicine. One explanation for this phenomenon was the obligatory emphasis upon the life threatening diseases. Now that our colleagues have obtained an impressive number of their health care research and delivery goals, the demands upon the comparatively underdeveloped health care specialties, especially otolaryngology, has paradoxically increased. The multiply handicapped child, the problem of the aging ear, the deafened and spatially disoriented ototoxic patient who survived his infection, the patient with no sense of smell and consequently no appetite, the stroke patient who can think but not speak or swallow normally, the blind and deafened diabetic to name but a few examples have steadily increased in numbers over the past two decades as a consequence of the longevity provided by advances in medical research and health care. Coupled with environmentally related ENT health problems (e.g. noise induced hearing losses and respiratory track cancers) the otolaryngologist and his colleagues have experienced increasing demands placed upon their present health care delivery system. Even if the knowledge required to optimally approach many of these problems were presently available, the special training required to administer advances achieved would require decades, instead of years, given the present status of research and training programs in otolaryngology.

The complement of researchers working in the basic sciences who provide the knowledge and principles upon which sound otolaryngology is practiced has never been optimal, because they have never been based upon national need or priority. There have never been adequate epidemiological data upon which program directors and granting agencies could set these priorities. Secondly, for reasons too complicated to relate here, the development of ENT related basic scientists lag years behind other medical specialties. The gap was just beginning to close when funds for training and research were curtailed. The net effect upon ENT research efforts was devastating. At the present time, ENT researchers consists of essentially two actuarially distinct groups. At one end of the age distribution lies the established senior investigator who has survived the cuts in grant fundings, while at the other, smaller end of the distribution both with respect to age and funding stands the dedicated fledgling investigator. There are very few "middle age" investigators working solely upon key problems in otolaryngology, thus a serious loss of continuity has occurred.

In order to illustrate from the practical viewpoint what has been and what could be accomplished, consider the following facts drawn from only one facet of a single ENT problem area. The early detection of deafness is essential if development of the patients' communicative skills are to be maximized. The yield (omitting false positives and negatives) for clinically significant hearing impairment is 1:500 to 1:1000 live births depending upon the population studied. This type of screening is typically carried out by newborn nursery staff or volunteers at insignficant costs. Compare this yield with some comparatively expensive screening programs for conditions that, with two exceptions, cannot be as satisfactorily treated or habilitated in comparison with the deafened: phenylketonuria 1:15,000; Combined immunological defects 25:3,000,000; maple sugar urine disease 1:300,000; neonatal hypothyroidism 1:6,000 (denominators refer to live births). Utilizing the cost effective type of analysis consider the following calculations. The manpower earnings lost to society because of deafness as presently treated is $4,000,000,000 annually. The earning capacity of patients who become deaf after the age of 6 is $1,208/year greater than the non-habilitated congenitally deafened. The difference between these two income capabilities ($1200 per year) multiplied by the 205,000 pre-lingually deaf subjects (a conservative estimate) yields an astounding $243,000,000 per year lost in additional income. Not calculated (because estimates are not available) are welfare and other social and medical maintenance costs for the deaf population. These costs may be considered the amount lost to society by failing to detect these patients at birth. The Department of Health, Education and Welfare estimates that care of the two million American deaf carries a cost of 1.8 billion dollars with an additional 11.6 billion dollars spent for care of millions with varying degrees of hearing impairment. Research funding for fiscal year 1978 for all of communicative disorders (including hearing related research) was only 21.2 million dollars, a parsimonious figure considering the magnitude of the problem and the cost of procrastination.

Otitis media is a far more common disease, ranking eighth on the list of primary care office visits. Assuming only one visit per year at an average total cost of $50/visit, a minimum of $500,000,000/year was spent for the care of otitis media patients in 1975. Less than $5,000,000 was spent on otitis media research in 1975.

Recommendations:

This brief presentation on the present status of otolaryngologic related research and health care delivery problems boils down to the following specific comments and recommendations.

1) A predictable and stable funding base for research and health care delivery for patients with communicative disorders should be established in order to provide continuous support for peer reviewed productive investigators. Without such potential equity and security, the prospects for attracting investigators to this field and keeping them throughout their productive careers is virtually nil.

2) Training opportunities in the field of communicative disorders should be available on the primary basis of merit rather than level of academic degree or area of specialization. The participation of students and scientists from many different fields will thus be encouraged as well as members of the professions including medical students who wish to expand their knowledge.

3) Limited numbers of specialized centers in the form of conceptually coordinated interdisciplinary research groups should be developed. This goal must be accomplished without reducing support for qualified individual investigators. Properly organized, administered and monitored, such centers would facilitiate communication between basic scientists and clinicians and thereby reduce the time lag between conception of new ideas and reduction to practice.

4) Allocate short term funds to enable additional studies for the purpose of developing expertise in specific new techniques. The astute scientist constantly updates his mind and techniques. The first task costs time, the second costs time and money.

5) Establish a strong intramural communicative disorders clinical research group within NIH. The logical setting for such a group would be within the National Institutes of Neurological and Communicative Disorders and Stroke (NINCDS). This group would serve as a model and resource for communication disorders scientists throughout the Unites States.

6) Provide the required administrative staff to adequately support NIH procedures and policies, monitor major health related priorities and recruit proposals from promising scientists.

7) Undertake extensive research in human genetics of communicative disorders. At present, there is no clinically efficient means to separate genetic transmitted disease from acquired disorders especially if only one sensory system is affected (such as the ear) as the sole manifestation of the defect. Because the relative incidence of congenital and acquired perinatal deafness tends to shift from time to time, it is important that such a capability be available to the health care community.

8) Develop effective methods and guidelines for clinical trials. The costs, risks and benefits of most otolaryngologic surgical procedures has never been determined.

9) Initiate extensive epidemiological studies in communicative disorders. These critical data have never been made available for most otolaryngologic diseases and disorders. These studies should obtain reliable incidence and prevalance data, determine the distribution of these disorders in the population, identify high risk groups and test hypothesis regarding the etiology of some communicative disorders. Given these data, cost-effective plans for the prevention, research priorities and health care delivery could be formulated.

10) Study, in both normal and abnormal states, the biophysics, mollecular biology, biochemistry and phyisology of the sensory transduction mechanisms. Several otolaryngology departments around the country have expended considerable departmental resources toward the development and support of scientists in these areas. However, because of the costs, a coordinated effort broadly applied to the many problems in otolaryngology is beyond a resources of individual departments or even regional efforts.

11) The characteristics of normal structure and function of many of the special sensory organ systems and their neural connections need to be identified and compared with the non-normal state. When the normal and pathologic anatomy and pathophysiologic mechanisms of the special sensory systems is compared with the state of development of this basic knowledge in the general body systems, the deficits are appalling. For hearing alone, the pathologic anatomy has been adequately described for only a few diseases.

Ladies and gentlemen of the panel, I convey the appreciation of all otolaryngologists and many patients for the opportunity to present our thoughts before you. We are prepared to document in detail the information contained in this summary.

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GOVERNMENTAL PARTNERSHIP IN APPLIED MENTAL HEALTH RESEARCH

Testimony Presented at the National Conference
on Health Research Principles

Clinical Applications and Health Services Research Panel

October 3 - 4, 1978

Barry Miller, Ph.D., Chairperson

State Mental Health Research Directors

National Association of State Mental Health Program Directors

My testimony today represents the views of the State Mental Health Research Directors Division of the National Association of State Mental Health Program Directors (NASMHPD). The National Association represents the Directors of the State's Mental Health Authorities. An as official Division of NASMHPD, the State Mental Health Research Directors Division represents the research interests and concerns of the State Mental Health Commissioners. The testimony which is to be presented today is entitled "Governmental Partnership in Applied Mental Health Research". It is to this partnership between the federal government and the State Mental Health Authorities in the area of applied mental health research that we would like to address ourselves.

States continue to be faced with demands for increased and improved services to care for the mentally and emotionally ill. Since state programs house the largest portion of mentally ill people across the nation (67% of the inpatient beds*), and states continue to accept and treat thousands of patients in state supported institutions (222, 525 inpatients*) as well as support thousands of patients in the state's community mental

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*Mental Health Statistical Note #144, DHEW, February, 1978.

health system, it is the position of the State Mental Health Research Directors that states have a responsibility to conduct research which will discover how mental illness can be effectively treated and prevented and a responsibility to continually study and improve the manner in which treatments are put into practice. Mental health problems effect millions of Americans and because we lack the answers to basic questions concerning the causes, treatment, and prevention of mental illness, we often end up providing only custodial care to our citizens at a cost of millions. In order to provide the ultimate goals of improved treatment and care in the future and the better quality of life to which our citizens are entitled, we must advance our understanding and technology in the area of mental illness. Research is clearly needed if we are to accomplish these goals.

Over the past two years, the State Mental Health Research Directors Division of NASMHPD has been very active in its attempts to bring these goals to the forefront. Two national conferences were held; numerous letters were written and several meetings were conducted with members of the President's Commission on Mental Health (PCMH) and the National Institute of Mental Health (NIMH).

Since the inception of the National Institute of Mental Health, a federal effort has been put forth to solve, through research, the problems which plague mental health and the delivery of mental health services. NIMH has not only developed its own intramural research projects, but has put a large effort into an extramural research program. Unfortunately, much of the external research effort by NIMH has been fragmented at best. In the vast majority of states, the mental health authorities are not even aware of what programs are being funded by NIMH within their own states.

In the final Report to the President from the President's Commission on Mental Health, the Commission reported that "although most State governments have either not invested in or are reducing the amount of money they invest in mental health research, we believe that they have a particularly pertinent role to play in the conduct of research. Research in the delivery of mental health services is one such area. The Commission recommends that:

> The Administrator of the Alcohol, Drug Abuse, and Mental Health Administration develop guidelines for providing Federal incentives to stimulate increased state support of research activities in mental health and related areas.

In order to implement this and other recommendations from the PCMH, NIMH has established a special Task Force. It is now, more than any other time in the history of State Mental Health Authorities, necessary to establish a "research" communication system with NIMH. More than ever, it is now important to monitor the flow of NIMH research funding to facilities within the states, and help coordinate this research effort and to help effect the transfer of research findings into clinical application.

State Mental Health Authorities are in an excellent position to help achieve these goals. State Mental Health Authorities occupy a unique and crucial position for doing research. States are more aware of the regional or state based problems and the research necessary for the accomplishment of their solutions; they have greater access to the data, populations and other resources needed to do research that is of practical value to the states (in some states only the mental health authorities can gain access to this data) and states are better able to support a continuity of inquiry through research institutes with state hired researchers. Only states can study the applicability and usefulness of nationally reported findings for their state's own particular needs.

The State Mental Health Research Directors believe that the public mental health system represented by the state government should have a commitment to mental health research. This commitment by the states should include the following:

1. A mechanism or formula for the flow of state dollars in support of mental health research.

2. A line of authority and responsibility for the promotion, screening and funding of research endeavors which involves the mental health authority of the state.

3. The establishment of peer review and quality control of research endeavors.

4. The establishment of priority review to ensure relevancy of state research to the needs of treatment and the delivery system of the state and provision for review designed to prevent duplication of efforts and to provide for orderly and adequate dissemination of research findings and the transfer of these findings into clinical applications.

5. A provision for the support and funding of both intramural and extramural programs to qualified researchers.

We are highly supportive of both the need for the DHEW Multi-Year Strategy for Support of Health Research and Secretary Califano's viewpoint that its development will enhance the research effort. We strongly support the fourth and fifth principles articulated by the Secretary in his April 29, 1978 address before the annual meeting of the American Federation for Clinical Research in San Francisco, California. As you recall, Secretary Califano's fourth principle was that government supported research must have a strong orientation towards improving the quality of our nation's health and the effectiveness of this nation's health services. We support this principle, because as Secretary Califano indicated, effecting this principle involves applied research that, in candor, has not yet reached its share of attention. Secretary Califano's fifth principle is that HEW supported research must be more effectively oriented to knowledge bases that support not just some, but all the health missions of the Department.

In particular, we feel that the high priority support for basic research in biology and behavior should be balanced by an equally strong commitment to applied research; i.e., investigations of the quality, efficiency and effectiveness of health services and their delivery system. There should be a coordinated effort between federal and state authorities in identifying the priorities for applied health research.

There should also be a strong commitment to developing and implementing methods of technology transfer. Without attention to such methods, research results can only slowly, if at all, infuse the public sector.

We believe that federal commitments to expand applied research and technology transfer, working with State Mental Health Authorities, can lead to substantial gains in the quality of mental health care and our ability to resolve many chronic and unresolved mental health problems.

We are not talking about the State Mental Health Authority doing this research, but rather developing a relationship with NIMH to support the process of defining priorities and developing a partnership in carrying out research in relevant areas.

Testimony Presented by:

Barry Miller, Ph.D.
Chairperson:
State Mental Health Research Directors
Division: National Association of
State Mental Health Program Directors

October 3 - 4, 1978

National Pharmaceutical Association
Presentation to National Conference on
Health Research Principles

Public Testimony on "Clinical
Applications and Health Services Research"
October 3, 1978
Joseph Hall, President

On behalf of the National Pharmaceutical Association I wish to present to you evidence to suggest that more research efforts need to be supported in the area of an assessment of the impact and value of clinical pharmacy services by the Department of Health, Education, and Welfare.

For the purpose of this presentation I would like to first define "Clinical Pharmacy": according to Parker,[1] "Clinical Pharmacy is a concept or a philosophy emphasizing the safe and appropriate use of drugs in patients." Usually it is not possible to pinpoint a precise time when a concept first becomes visible. Gloria Francke, in her review of the literature, pointed to the University of Washington experiment of 1944 as the probable origin of the clinical pharmacy concept; in which pharmacists were placed on a patient floor and monitored drug therapy. [2,3] One can conclude with reasonable assurance, however, that "clinical pharmacy" emerged in mid-20th century american pharmacy and by the mid- 1960's the concept had developed to the point where it could be seen but not necessarily understood.

As with any business or institution, inflation has caused administrators and policy decision - makers to examine more closely the cost - benefit impact of any new program. Unfortunately, the profession of pharmacy has not sufficently begun to critically evaluate and demonstrate the effectiveness of its practitioners and current precepts in delivering various innovative pharmacy services i.e. clinical pharmacy services. Economists and others have suggested that cost - effectiveness and cost - benefit analyses are necessary to adequately evaluate additional health care services that would result in increased costs to the system.[4] However to demonstrate the effectiveness of clinical pharmacy services, DHEW should be concerned about funding more research projects that use the tools of cost - benefit analysis to demonstrate the benefits of innovative pharmacy services; thereby increasing the acceptance of such programs by the medical profession, third - party payers and the consumers.

At this point I would like to share with the group a brief review of some of the studies that have been published recently demonstrating the cost - effectiveness of certain select innovative pharmaceutical services.

Ambulatory Patients and Therapy Responsibility

Although not conducted with a cost-effectiveness format, McKenny et al studied the effect of clinical services provided by a pharmacist to 25 patients with essential hypertension compared with 25 patients not receiving the pharmacists service. Results showed a significant improvement ($p < 0.001$)

in patients knowledge of hypertension, compliance with prescribed therapy and the number of patients whose blood pressure was kept within the normal range. It was concluded that the pharmacist's services were benefical and that pharmacists should become more involved in ambulatory care of this nature. The amount of total time needed by the physican control group and the pharmacist experimental group seems to show that pharmacists decreased the need for intensive follow-up services which may add to favorable cost-effectiveness if this economic techniques had been applied.[5]

Unit Dose and the Pharmacists.

The U.S. General Accounting Office had concluded, in a comparative analysis of all annual cost elements in unit dose and traditional ward stock systems, that high prescription levels of over 25,000 unit doses had a lower overall cost than ward stock systems. Hospitals with 400 or more beds generally fall into this latter category. The favorable cost-benefit ratio is achieved through reductions in nursing time spent preparing and administering medications. The study concluded that additional benefits of unit dose may override economic considerations at all drug-volume levels, regardless of quantifiable costs factors. Additional benefits would include improved patient care, reduction in medication errors, and a closer relationship between physican and pharmacists.[6]

A comprehensive unit dose study was carried out by Smith at the Long Beach Memorial Hospital. Although this was also a study of clinical pharmacy services in a community hospital, it mainly demonstrated the positive benefits over operating costs of a unit dose system by saving nursing time. The $56,000 per year saving in nursing salaries was reduced after pharmacy personnel were fully salaried. The cost figures apparently did not include start-up and conversion costs which would have to be amortized on the cost side over several years in a full cost-benefit study.[7,8]

Drug Information Services

Bell et al studied physicans' acceptance and use of a pharmacy drug information service.[9] They found that physicians did indeed accept and use the information related on product dosage, drug interactions, adverse reactions, contraindications and drugs of choice. Regression analysis of certain independent variable suggested that pharmacists tended to initiate successful communications regarding patients who were receiving more drugs, greater variety of laboratory tests and requiring longer periods of hospitalization. One-fourth of the patients included in the study benefited from information provided by the pharmacist. Physicans responded very positively to the service, but cost-effectiveness was not discussed in this study.

Monitoring Drug Therapy (Acute Care).

Dick et al carried out a cost-effectiveness comparison of a pharmacists using three methods for identifying possible drug-related problems (PDRPs).[10] They found that chart review costs $5.30 per PDRP, attending patient rounds with physicians $8.68 per PDRP and patient drug profiles were $1.06 per PDRP. Patient profiles were the least expensive, but only 6% of the PDRPs were judged to be significant by an interdisciplinary expert panel. Over half of the PDRPs found while attending patient rounds with physicians were found to be clinically significant. Chart review was in the middle of these two in effectiveness.

Monitoring Drug Therapy (Long -term Care).

Cheung et al studied the impact of clinical pharmacy services in skilled nursing homes facilities.[11] The study was carried out in four facilities with one of them serving as a control. The project was evaluated by an interdisciplinary team. The medication error rate dropped from 20% to 8%. Medication orders per patient were reduced from 5.9 to 4.6, which decreased drug costs by $25,000 per year. Cancelling unnecessary drugs saved an estimated $10,000 per year. In addition, it was estimated that 70 serious adverse drug reactions were prevented. This represented a cost saving of $49,000 a year (4-7 days stay/ADR x $100-150/day in hospital). Thus for the 300 patients surveyed, it was estimated that $80,000 were saved per year. This is about $0.73/patient day saved. Although not perfect, this often is quoted as the most encouraging cost-effectiveness study thus far.

Patient Discharge Interview

Ryan et al evaluated savings experienced by patients as a result of the pharmacists performing a discharge medication interview.[12] The study involved 1,000 patients on a surgical service. Pharmacists worked with physicians to perform tasks such as substituting less expensive drugs and securing third-party coverage for eligible patients. Savings of nearly $1,700 were realized on 517 of 1.832 prescriptions which equaled a

$9.13 savings to patients per hour of pharmacist's consultation time. Costs and other benefits were not measured in this study, but if only salary is considered and if the pharmacist's salary was less than a total of $9.00 per hour or $18,000 per year, the benefits of this service might be considered to exceed the costs.

Patient Profile Systems

Zelnio et al found that patient record systems can be cost-beneficial.[13] Gagnon, in a previous survey, found that consumers placed an average value of $0.15 per prescription on the benefits of patient profiles. The variable cost for supplies and fixed costs of different patient record systems averaged $0.03 per prescription and $377.44 respectively. Various labor costs also were calculated and it was found that, if the increase in labor is no larger than 10%, chain pharmacies with daily prescription volumes of more than 75 and nonchain pharmacies with daily volumes of more than 40 prescriptions can profit from this service. In finding that the estimated benefits of patient records exceeded the estimated costs, the authors concluded that the market will bear a $0.06-0.20 increase in price per prescription as reimbursement for this service.

Cost of Multiple Patient Services

Munzenburger et al investigated the cost/impact analysis of selected clinical functions in three hospitals. [14] Pharmacist were assigned to medical units within each hospital. The pharmacists participated for seven days a week and data were collected during 62,40-and 44-day study periods. Results revealed that a patient could receive all four clinical pharmacy services-admission drug history, monitoring patient drug therapy, drug information and discharge consulation-for $5.50, $9.10 and $5.54 at the three hospitals respectively.

If one were to fully examine the various types of innovative services that pharmacists could provide, one might categorize these services as follows.[15]

1. Ambulatory patient consultation,
2. Unit dose drug distribution,
3. Drug information services,
4. Monitoring drug therapy (acute care),
5. Monitoring drug therapy (long-term care),
6. Parenteral admixture services,
7. Patient and therapy responsibilities,
8. Patient discharge interviews,
9. Patient drug histories and profiles and
10. Personnel substitution.

Conclusion

In the early 1970s, pharmacy leaders called for more evaluation of the benefits versus costs of pharmaceutical services; the literature reflects evaluation attempts in this regard. The literature is just the tip of the iceberg because it appears that pharmacists have been able (supposedly on a cost-benefit basis) to convince health care administrators in some programs to provide financial support for innovative services. Not only are pharmacists remunerated for consulting in skilled nursing homes, but Blue Cross in Ohio now reimburses pharmacists for patient consultation for home treatment in the areas of parenteral nutrition, calcitonin therapy, cytarabine therapy and hemophilia.[16,17]

Despite several encouraging reports on the cost-benefit of pharmaceutical services, more evaluative research is needed to develop programs which maximize the benefit-to-cost ratio to society. Even though a pharmacy endeavor may be able to demonstrate positive benefits over costs, we must realize that society ultimately will invest its resources in needed programs which have the higher benefit-to-cost ratio. In a related vein, we must convince the health system and the patient that these pharmacy services are worth using with modification or deletion of programs where necessary.

Recent consumer surveys which measured acceptance of new pharmacy roles demonstrate that more efforts must be undertaken to gain consumer acceptance of innovative pharmaceutical services.[18,19]

Progress is being made in the application of cost-benefit and cost-effectiveness principles to the expanding roles of the pharmacists. More study and analysis is needed, however, because sound cost-benefit studies are necessary to provide the cruical documentation for pharmacists in their efforts to be fully used in the health care system.

Thank you

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PROVIDING HEALTH CARE

FOR UNSERVED AND UNDERSERVED ETHNIC MINORITY COMMUNITIES

Carrie F. Rogers, National Black Nurses Association

Problem

Many areas of the Black Community have a major segment of its population who are unserved and/or underserved in the health care industry. Various means have been initiated by public health services, Black and White health providers, and others to impact the underserved and draw them into the mainstream of health care with varying minuscule degrees of success.

Research to determine how this barrier can be effectively penetrated and health care effectuated is necessary if our aspiration is quality health care for all Americans.

Proposed Solution

An indepth community based analytical study is needed to investigate the following points.

1. What are the barriers to minority populations seeking and/or accepting health care on a regular basis as opposed to participation in crisis care only?
2. Who are the appropriate care givers to maximize availability of community based health care?
3. How can the health care community-at-large effectively reach those who are unserved?

The proposed study would investigate these and other points by the use of the following techniques.

1. The population to be studied could be selected as a cross-section random sampling, according to geographical location, economic and educational status, and the availability of health care in their respective locales.
2. Careful documentation would be kept on the frequency, reason, and cost of their exposure. (i.e., physicians' offices, emergency rooms, ambulatory care, etc.)
3. Outcomes would be carefully evaluated. The indicators (attitudes by the client about the services received, outcome of visits, and

general health status) would be analyzed and based on the body of data accumulated during the longitudinal study. Recommendations could be drawn concerning the most efficient, highly utilized type of service(s) that are best responded to by those studied; what hours, etc., were most advantageous for maximum usage; and who delivered the care.

Problems

The major problem inherent in considering this study would be validation of a community's needs based on and/or defined as being under and/or unserved. Monetary consideration for a period long enough to assure sufficient data collection time, and the right persons to concentrate on the project are necessary. The methods of documentation and measuring outcomes should be consistent; therefore, the tool to ensure uniformity must be developed.

Benefits of the Study

The expected benefits of conducting this study would be a healthier community through exposure and re-education. It would, hopefully, afford innovative methods of reaching and caring for the unserved. Over a period of time, it should prove cost efficient by reducing the number of hospital days spent in crisis care.

BIRTH CONTROL PILLS

Effect on Teenagers and Young Adults

Personality Changes and Labile Behavior

Problem

The teenage and early adult population on birth control pills are subject to mood swings as severe as some premenopausal women. Is this labile behavior a direct result of the effects of the "pill" or is the behavior due to physiological changes and would it occur anyway? The consequence of this behavior must have bearing on the number of teenage "runaways" and "throwaways". A long-term study on the effects of the "pill" on teenagers is necessary to substantiate advocating the use of this method for birth control for teenagers.

The entire area of puberty and pre-pubescence deserves consideration in the area of biochemical research in view of the numerous problems identified and the scarcity of solutions to most of these.

Other areas to be considered:

-Teenage Suicide—Why the increase?

-Recruitment and Retention of Minority Students in the Medical Professions

-Prenatal Care and the Concept of Regionalization

-Nutrition
  a. The effects of Nutrition on the Elderly with Chronic Brain Syndrome Would good nutrition delay the process?

-Home Health Care As a Viable Cost Effective Adjunct to Hospital and Institutional Care

TESTIMONY ON "CLINICAL APPLICATIONS AND HEALTH SERVICE RESEARCH" FOR THE CONFERENCE ON HEALTH RESEARCH PRINCIPLES

BY: MAX E. CHILCOTE, PH.D., AND ROYDEN RAND, PH.D.
FOR THE AMERICAN ASSOCIATION FOR CLINICAL CHEMISTRY

My name is Max E. Chilcote. My credentials may be briefly expressed as a doctorate in biochemistry, many years in the Department of Biochemistry at the State University of New York at Buffalo, and some twenty years at a university affiliated hospital and laboratories, which institution I now serve as Director of Erie County Laboratories and Clinical Professor of Biochemistry and Pathology. I am also the current chairman for the Committee on Professional Relations for the American Association for Clinical Chemistry.

I have with me Royden Rand. His credentials include a doctorate in biochemistry, and more than 20 years in the field of clinical chemistry, working in the hospital, independent laboratory and industry. He is a past-president of the American Association for Clinical Chemistry. Currently, he is supervisor of clinical chemistry, Health, Safety, and Human Factors Laboratory, Eastman Kodak Company. We are representing the American Association for Clinical Chemistry.

Our objective in this brief testimony is to argue for renewed support of cooperative research between government, industry and university-related clinical laboratories; and in more general terms, for the fiscal support of clinical applications research programs. The patients of each generation deserve to benefit from the findings of basic research of that generation. This is not possible unless the gap between the basic research and clinical application is very considerably decreased. Only federal funding of clinical applications research can do so. The absolute control of research funding by those interested only in so-called fundamental research must give way to some significant extent to those interested in improving the patient care of today and tomorrow. We will attempt to illustrate the success of applied research efforts in the following remarks.

The research program of the Body Fluids Division of the Oak Ridge Molecular Anatomy Program is to the best of our knowledge the best example of cooperative research between government and industry in terms of its current and long range beneficial effects on laboratory medicine. As specific examples, both the centrifugal parallel fast analyzers (GEMSAEC) and the High Pressure High Resolution Liquid Chromatographic (HPLC) systems were developed there under the guiding genius of Drs. Norman Anderson, Charles Scott, and colleagues. The Parallel Fast Analyzers have already attained a well established and valuable place in many, many clinical laboratories - especially in the production of accurate, specific results in the assay of many enzymes. Similarly, liquid chromatographic systems are rapidly finding an important place in body fluid analyses. As a matter of fact, the role of these chromatographic systems in the monitoring of therapeutic drugs is to us a most exciting development in clinical chemistry. To note just one example, a study by Marjorie Hornung noted, some 5 - 6 years ago at the Oak Ridge meetings - that there were several thousand children in both the Rochester, N. Y. area and the Houston, Texas area that were being treated with anti-convulsant drugs, and that monitoring of their blood levels of these drugs was yet too difficult to be readily available. High pressure high resolution liquid chromatograph is now doing this job in many clinical laboratories quickly, reliably and inexpensively.

However, the process of bringing the initial research to final application in the clinical laboratory required development of these instruments to practical production models and then their refinement through testing programs in the clinical laboratories. The Clinical Chemistry laboratories of the Erie County Laboratories served as a major field testing laboratory in the testing of a number of prototypes in Union Carbide's development of Centrifichem - their version of the centrifugal parallel fast analyzer. In this process, we initiated studies on procedures for many analytes of clinical interest, e.g., cardiac and liver related enzymes as well as metabolites such as glucose, bilirubin, etc.

However, it is most important to note that the above cooperative research would not have been possible without the presence of post-doctorate trainees from our "Training Program in Clinical Biochemistry", and that their salaries were funded through a grant from the Institute of General Medical Sciences. These trainees were necessary as our own full-time clinical chemists were almost completely occupied by service functions. This happy combination was found, of course, in more than our own institution. These trainees produced research results that were quickly applicable to the care of human patients. Because of these efforts, we were also able to produce highly trained specialists and found useful professional employment for them.

We have, to date, graduated thirteen from our post-doctorate training program in clinical biochemistry and all have found employment in academic laboratory medicine, the private independent laboratory sector, or in related analytical apparatus industry. Our own County of Erie has supported and continues to support the salaries of two such trainees, but these are threatened by current fiscal constraints in the health care systems that are separating the cost of education from patient care costs. We could really put to very good use continued funding of our training program.

We recognize that we have cited just two examples of the value of support of clinically applicable types of research in laboratory medicine. They demonstrate, in our opinion, that investment in new, innovative analytical technology can and does result in benefit to the patient, even though the benefits are not clear at the time of invention and development.

There are other numerous problems related to the application of clinical laboratory technology that need research and development. Examples of these are: 1) Interpretation of laboratory data. The modern clinical chemistry laboratory can analyze biological fluids for a staggering number of substances, many of which involve methods of great sophistication. Modern computer technology and decision theory has shown the potential of substantially enhancing the information content of these data. Further research could yield strategies for improved diagnostic effectiveness and the monitoring of therapy. 2) New tests. The medical literature continues to report new tests.

Current examples are hemoglobin A_{1C} in diabetes, a bewildering array of potential cancer markers and high density/low density lipoprotein relationships in atherosclerosis. Applied research support might very quickly and effectively show how these could benefit patients by yielding more precise diabetes control, more sensitive cancer diagnosis and therapy and a more sensitive predictor of vascular disease. 3) Precision and accuracy. Closely related to the problem of more effective interpretation of laboratory tests is the potential need for tests of improved accuracy and precision. The history of science is replete with numerous examples where improved measurement precision and accuracy yielded significant new knowledge and understanding of scientific phenomena. Research is needed to quantitate the real needs in clinical chemistry as well as means of obtaining improved precision and accuracy. We, also, call to your attention the strong support provided by the American Association for Clinical Chemistry to problems of precision and accuracy. The Association has contributed significant amounts of money and its members have voluntarily given untold hours in study of the many problems related to this important subject. 4) Cost/Effectiveness. The American Association for Clinical Chemistry has strongly supported government efforts to control escalating medical costs. Recently, Medicare has initiated effort to reimburse providers of medical laboratory tests at so called "lowest charge levels." The relevant documentation in the Federal Register conceded the inability of the Social Security Administration to provide suitable quality standards which might be related to appropriate charge levels for laboratory tests. We argue that research is urgently needed in order to provide the data and information which would allow a meaningful setting of lowest charge levels, with understanding of requisite quality.

These four examples will suffice. In summary, we think that in the area of clinical applications that: 1) Past support of new clinical laboratory technology development has yielded substantial benefits, 2) Many pressing problems exist, the solution of which would directly benefit the American public and even, perhaps, control costs. We thus, recommend for your consideration, that a significant allocation of research funds to the clinical laboratory should become one of the new principles for the support of health related research.

Thank you, Mr. Chairman, for the allocation of this time.

FOCUS 2: CLINICAL APPLICATIONS IN HEALTH SERVICES RESEARCH

Presented at the National Conference
on Health Research Principles

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National Institutes of Health
Bethesda, Maryland

Presented by Maurice Wood, M.D.

for

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INTRODUCTION

The Society of Teachers of Family Medicine is comprised of approximately 1,440 members, all involved in family medicine education and training programs. It is an interdisciplinary society with members representing medicine, social work, education, pharmacy, administration, nursing, the behavioral and social sciences, and other fields. Our members pursue their professional activities in medical schools, community hospital teaching programs, and in a great variety of community-based teaching practices. In the Spring of 1978 the Research Committee of the Society was charged to review and articulate principles and strategies which might profitably govern the research efforts of those in our discipline. That work began during the past Summer and was accelerated in response to Secretary Califano's request for input into the development of a federal strategy for supporting health research. The document presented here has been prepared by a task force of the Society and will be submitted to the organization's Board of Directors at its next meeting in October, 1978. Many of the members who are involved in research also participate in the North American Primary Care Research Group. This testimony is a joint effort of these two organizations.

FOCUS 2: CLINICAL APPLICATIONS IN HEALTH SERVICES RESEARCH

Except for the following, where modifications are requested, the draft principles as written, are supported.

"The scientific merit of health services research is a necessary condition for support". (NCHSR) *(but consideration must be given to the state of the art in each particular field of inquiry)*

"Provision of flexibility for innovative proposals". (NCHSR) *(This principle does not address the innate ridigity of the present peer review system)*

The following represent suggested new principles and their justification.

-"To describe and investigate the process and outcomes of continuous community-based care of chronic, disabling and degenerative disease in people of all ages".

Such patients enter hospital infrequently. Their disease or disability stabilizes and the caring process consists of keeping them at the highest plateau of function possible. Such clinical investigations must be undertaken in a controlled practice environment in the community where long-term relationships between the providers and the patients have been established, where instruments have been developed which allow a measure of statistical control of the environment which equates with that available in the hospital.

-"To develop an accurate knowledge base of the natural history of the presentation and evolution of common, serious and life-threatening diseases in the community".

Little information exists, based on observations undertaken in the primary care setting. Such knowledge will allow the effects of special interventions in the natural history of some of these diseases, and the effects of family structure on the morbidity of the individual and of individual morbidity on family function, to be determined.

-"To improve the quality of care by research into the social etiology and the ecology of disease, and to examine the social components of therapy and rehabilitation in acute and chronic problems cared for in the community setting".

Little information exists on the specific effects of social disburbance and of social and environmental change, on health and illness. Research will address the effects of such elements as, geographic site of residence, the length of stay in one place, and the exposure to work and atmospheric pollution on the morbidity of populations, compared with the morbidity of similar populations in other settings.

-"To develop instruments to describe and classify the reasons why patients use primary care health services. These will include: glossaries of terms and definitions, classification of signs and symptoms, of impairments and handicaps, of lay terms, of risk factors, and of family structure and family illness".

The classifications of disease presently in use are biomedically oriented, and largely ignore the behavioral and psychosocial elements of ill health, which are particularly significant in primary care. Symptoms, signs, and biomedical diagnoses may be used as "tickets of admission", masking behavioral and psychosocial problems. Appropriate classifications will enable comparison between patient's reason for visiting the provider and the problem defined after investigation by the provider.

-"To develop an adequate knowledge base to determine which health care specialties are being utilized for what by whom".

Research will answer questions as to whether the primary care specialties do deliver continuous comprehensive care and how the consumer and family uses that care. Such research will require multi-year funding and should be undertaken in community practice environments equipped with methodologies for statistical control.

-"To conduct research into the cost effectiveness and quality of care, in alternate primary health care delivery sites and organizations".

Such comparisons are necessary to decide on the most appropriate type of organization for the provision of primary care in various circumstances. Comparison of single specialty primary care organizations and multi-specialty groups, solo vs. group practice, and fee for service vs. prepaid health care would be appropriate.

-"To conduct research into medicine as a social institution".

This will allow the analysis of the health care team, practice structures, research into medical student training and role learning, and the longitudinal assessment of student characteristics which predict a career in primary care.

-"A strategy must be designed to influence the individual to accept more responsibility for his own mental and bodily health".

There is an increasing proportion of illness and disability due to the effects of inappropriate lifestyles.[1] The non-use of seat belts in cars and the development of the degenerative diseases due to inappropriate eating and exercise habits represent deficiencies in the personal responsibility of the individual to society.

-"A strategy must be developed to produce population-based morbidity data from the national scene. New methods such as the use of the "sentinel practice"[2] system need to be considered".

Such information will measure the regional differences in both quantity and characteristics of demand. It will help determine the appropriate mix of primary and sub-specialist provider manpower necessary to meet the demand in the most cost effective way.

IN SUMMARY:

1. Primary care research practices with defined patient populations are effective institutions for clinical, epidemiological and health services research.

2. The production of classifications and glossaries to describe and classify the structure, process and outcomes of primary care should be supported.

3. Research into the process and outcomes of community-based care provided in a continuous, comprehensive manner for people of all ages, is imperative.

4. Primary care can provide preventive, promotive and predictive continuous care which may influence the prevalence of acute and chronic disease and injury in defined populations.

[1] A New Prospective on the Health of Canadians, 1975, Marc LaLonde
Ministry of Health Canada

[2] Continuous Morbidity Registration Sentinel Stations Annual Report 1970-76. Program Leader: Bertien Collette, The Netherlands Institute for General Practice, Postbus 2570, 3500 GN Utrecht, The Netherlands

Name: Thomas E. Morgan, M.D.
Affiliation: Association of American Medical Colleges
Panel: CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

I am Thomas E. Morgan, M.D., Director, Division of Biomedical Research, Association of American Medical Colleges. I am pleased to appear before this Panel to present the views of the Association of American Medical Colleges on maintaining and strengthening the biomedical and behavioral research capability of this nation. The Association has provided to the Department extensive, carefully considered remarks on the subjects of applied and targeted research. The AAMC position was developed with input from more than 40 professional and academic societies. Because of the severe limitation of time available in which to present our views to this Panel I must confine myself only to the recommendations of our Association, however, I have sufficient copies of sections of our Biomedical and Behavioral Research Policy statement which bear on the problem before you so that you may each have a copy at this time to aid your deliberations.

For many years basic and applied research have been initiated primarily by the investigator, and Federal support of this research has been generally organized along disease or organ system-oriented program lines in the Institutes of the National Institutes of Health. The systemic, disease-oriented programs of these Institutes enjoy the support of the Congress with the resultant creation of legislative authorities targeted on specific diseases. More recently other authorities have mandated clinical trials, research and demonstration centers, and disease-oriented programs on an unprecedented scale. The new authorities for the National Cancer Institute, for the National Heart, Lung and Blood Institute and, to a lesser extent, for programs such as Arthritis and

Diabetes are examples. These legislative authorities have been implemented to a large extent through targeted research programs using a combination of research contracts and center grants. Such targeted research has caused tension and competed disproportionately for funding with basic and applied research initiated by investigators.

The trend to establish research and demonstration centers targeted on specific diseases has required NIH and the performer institutions to plan demonstration projects which, though not new either to the academic medical centers or the Public Health Service, have had an uneven record over the last two decades. This suggests the need for a more thorough and objective assessment of past failures and successes and a careful analysis of such essential factors as the state of scientific knowledge, the identification of target populations and the adequacy of trained manpower and other necessary resources. These programs have also posed difficult problems within the academic medical centers and NIH where the managerial talents peculiarly required for these specialized functions were not available, despite the array of scientific talent in those institutions.

All of these changes have created undesirable competition for program funding priorities among basic, applied and targeted research. Targeted research in general and research and demonstration centers in particular have had a negative effect on the priority given to fundamental research. The AAMC believes that the Congress, the Administration and the research community should clearly enunciate and periodically reaffirm a commitment to each of these types of interrelated research.

Name: Thomas E. Morgan, M.D.
Affiliation: Association of American Medical Colleges
Panel: CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

The AAMC therefore recommends:

- A vigorous program of high quality research applied to clinical problems should be supported by Federal grants, private philanthropy and by industry.
- AAMC strongly endorses the investigator-initiated project grant as the most appropriate mechanism of support of basic and applied research. Consequently, investigator-initiated projects should have priority over centrally directed funding mechanisms which are more appropriate for clinical trials research/demonstration centers and other targeted activities. Any erosion of support for investigator-initiated activities, regardless of cause should be immediately remedied.

With respect to the transfer of fundamental knowledge to the care of patients and the prevention of disease I have furnished you a detailed appraisal of this complex process and the role which the NIH, other federal agencies and the private sector should play in it. At this time I will merely summarize our recommendations.

Research directed toward the discovery of new knowledge, to its application to medical or health care and to determining the validity, safety and efficacy of new technology is very important. Such targeted research merges with demonstration and dissemination of proved technologies as part of the process of technology transfer. These latter transfer activities are expensive in terms of time, money and personnel and they are difficult to devise and control. Although support of biomedical research is the primary mission of the NIH there has been a tendency during the past five years to expect NIH to assume these additional technology transfer responsibilities for lack of a more appropriate organizational alternative.

Name: Thomas E. Morgan, M.D.
Affiliation: Association of American Medical Colleges
Panel: CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

In the important area of health services research the AAMC believes that although schools of public health, among the other components of universities, can contribute to health services research, the close contact of medical schools with patient care gives them a large advantage in such research and its applications to improving the health status of the nation.

The AAMC therefore strongly recommends:

- The transfer of research-proven technology to health care should be the mission of a number of Federal agencies, private organizations and industry. A fund for the support of technology transfer activities should be created and related to the health care budget. It should be administered by an agency responsible to the Assistant Secretary of Health assisted by an advisory council.
- An appropriate mission of NIH is the support of targeted research through the use of selected clinical trials in appropriate areas and interdisciplinary centers.
- NIH or other Federal agencies should be charged with the development of low-profit technology. NIH should participate in developing demonstration and education strategies and should also participate in supporting the training of the specialists needed for this mission.
- The research mission of NIH should not be compromised by adding the requirement that it serves as the primary agency for technology transfer.
- Medical schools, working with other components of universities including schools of public health, are the proper locus of increased research and analysis of health care delivery.

Dr. A. Hollis Wolf American Osteopathic Association

The Osteopathic Profession feels it should now shoulder its share of the responsibility for good medical research, particularly in a long neglected area of the relationship of the musculoskeletal system to the general body functions.

All forms of medical practice have had the common experience of utilizing some modality and/or medication, only to find surprising results, not necessarily related to the problem in mind, when such treatment was given. Many effective treatment measures have resulted from the observations of a clinician. Many instances are at hand of research coming "after-the fact" to explain the mechanism by which some successful measure operated.

For nearly a hundred years, Osteopathic Physicians have used manipulation of the musculoskeletal system in the treatment of many systemic disorders. The inadequacy of medicines available at the turn of the century caused the early D.O. to emphasize the inherent ability of the human body to meet the stress of disease, with its own defense mechanisms, when means were found to facilitate such response.

Thus, the early D.O. found himself depending on manipulative procedure as his primary therapeutic measure for such things as bronchial asthma, pneumonia, cardiac disease, peptic ulcer, renal disease, and nearly all other visceral disorders. His signal success in the infamous "flu" epidemic of 1918 is a matter of record.

Osteopathic clinicians have, through the years, observed many such interesting results. Unfortunately, however, scientific evaluation of such impressions is, at best, poorly substantiated. The Osteopathic clinician knows he can favorably affect visceral function, but the mere reporting of an impression as to how a patient feels is, sadly, a poor substitute for scientific research.

The musculo-skeletal system profoundly affects every function of the human body. One scientific paper even pointed out that the fasciae are the location for the electrolyte storage of the body, authored by an M.D., for example.(1 Stress on fascial planes, on muscle strata, all place a deleterious effect on lymphatic and venous drainage, for example. The increased sensitivity at a given segmental level, of the spine, has already been conclusively shown in objective research projects, and this neurologic influence is known to affect visceral function. Learning how to utilize these physiologic mechanisms for maintainence of health and/or treatment of disease is the primary contribution of the Osteopathic profession.

We feel that properly trained investigators and observers can produce information that will show how the human body responds to various stresses, how to improve this body's own physiologic mechanism's role in recovery from disease, and how to minimize the use of foreign substances which, all too often, have more side-effects than the disorder they were designed to treat.

The Osteopathic profession, for years, has financed its own research projects, but the task is a stupendous one. We have, in our several colleges, and numerous hospital, numerous personnel to do this job. It requires much more equipment, many more ancillary personnel, and a tremendous amount of finance. These researchers are involved in basic research as well as the clinical application area of research.

We feel we have a wealth of background in this approach to health problems, and welcome the opportunity to develop scientific data to authenticate, or disprove if it so be, the ideas we have gained from a hundred years of experience.

A. Hollis Wolf, D.O., F.A.A.O., F.A.C.G.P.
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AMERICAN OSTEOPATHIC ASS'N

1. CHESTER S. KEEFER, M.D.
MEDICAL CLINICS OF NORTH AMERICA
SEPT. 1951

CAFFEINE FROM THE 986th WITNESS

Kent W. Peterson, M.D.
American College of Preventive Medicine

Today we sit on ivory seats,
noble science to entreat.
Health research principles we debate
by behest of Califano and, of late,
Don Frederickson with all his weight.

In 20 years the dollars spent
have brought us health and life content.
"Not true" some jaded skeptics say?
We know more basic research may.
When life and health are now at stake
and dollars can the difference make.

How dare the Congress to suggest
areas of need for grant requests.
If our priorities we must declare
we cannot equally the resources share.
Indeed...our values will lie bared,
our search for truth will be impaired.

Let's collude to find a way
to advocate with noble sway
research principles broad and grand
with flexibility throughout the land,
while investigators regain an upper hand.

This poem was hastily drafted this morning, when I discovered my testimony would follow that of a great many witnesses. It is intended to provide the panelists a bit of good-natured relief during this intensely serious task of defining what we researchers most value. In addition, it reflects several points I would like to restate in prose.

We should all be grateful to Secretary Califano for stimulating the reassessment of our strategy for allocating government research dollars. It is gratifying to see much of his thinking so subtly woven into the language of these reformulated principles. This is especially true for us in preventive medicine, an arena in which the public has such great expectations which often exceed the established research base.

I urge you to consider three points. First, war may be emminent. If these principles are to be more than a "concensus in the sky", as some consider this conference, fundamental changes are needed in research priorities. The only condition under which they may be achieved without conflict is if funding for all health research is markedly increased. To predict this is, I believe, naive. Despite our collective efforts, prospects for a more limited growth economy suggest a higher probability for a net decrease in health research dollars. And scarcity tightens the screw of resource allocation to a point where gentlemen (and women) fight fiercely for what their values dictate.
The recent NIH leadership has leaned disproportunately in favor of fundamental biomedical research, relegating to embarrasingly low levels of support the other seven applied areas of the "full

spectrum of health research" outlined in the introduction to the Conference report. An example of HEW's neglect is health services research dollars, which declined from$80 million (out of $1 billion) in 1970 to $40 million (of $2 billion) in 1977. Other areas of applied "clinical" research have been given similar short shrift. The proposed principles are fine prose, but John Dillinger had a knack for going where the money was. I urge you to add a clarion call to your section of this report to substantially increase the proportion of resources devoted to applied and health services research.

My second suggestion is for you to expose and modify a subtle, but profound, bias in the logic of this report, namely, that in the "research continuum" there is an orderly one-way flow of information from the "fundamental" knowledge base areas to the arenas of applied "clinical" and health services research. In accomplishing our mission of reducing human suffering, and increasing the opportunity for joy, professionals often profess too much on behalf on those we serve. Clear pathways must be established for communicating research priorities from the clinic, home, school, workplace and community to the bench laboratory. An internal measure of accountability can be provided by having those engaged in the full spectrum of research, including clinical and health services research, be represented on peer review bodies and those determining research priorities. This will enable creative mechanisms to be developed to link fundamental and problem oriented research.

My final point is poetry itself in its brevity. Education should be integrally linked with research. Each research center should develop or support educational clearinghouses and learning activities for practicing professionals to disseminate new knowledge in usable form.

I shall close with a mystery statement of Buckminster Fuller, who captures the paradox of creative research looking both backward and ahead at the same time. We seek designs that are "more adequately anticipatory of the probable reoccurrence of yesterday's experiences".

Name: Dr. Francis B. Palumbo
Affiliation: American Association of Colleges of Pharmacy
Panel: Clinical Applications and Health Services Research

My name is Dr. Francis B. Palumbo of the University of Maryland School of Pharmacy. I am representing the American Association of Colleges of Pharmacy which is made up of faculty members and administrators of the nation's 72 colleges of pharmacy. The Association is pleased to have this opportunity to comment on proposed research principles for the Department of HEW.

The Association is particularly interested in the topic of clinical applications and health services research. The faculty of our colleges of pharmacy are heavily engaged in applied research, including both the clinical and health services research areas. Our graduates, the practicing pharmacists of the country, are constant users of the products of this research, that is, knowledge about drugs and their use.

Thus, it is no surprise that our Association supports the principles put forth in the planning document, especially the call for "...specific program expansions for the support of clinical applications, clinical trials and health services research activities." One appealing specific approach would be the creation of a National Institute of Clinical Pharmacology and Clinical Pharmacy, as proposed earlier this year by Senator Edward Kennedy of Massachusetts.

Additional support appears especially necessary for health services research. The most casual inspection of federal outlays for research reveals that the budget for the National Center for Health Services

Research is but one-one-hundreth of that for the National Institutes of Health, and that this figure itself is less than a third of NCHSR's budget five years ago. Although this is not the only federal agency which supports this type of research, it is clear that health services research requires more support if the important goals espoused in the statement of principles are to be met.

One of the principles put forth is that preventive and therapeutic measures should be validated before their introduction into the health care system. While this is an admirable goal, it is clear that the only area in which this is accomplished presently is that of the evaluation of new drugs prior to marketing. The only reason it occurs for drugs is because of specific legislation. Since it is highly unlikely that any other area of health care will be as stringently regulated as drugs, more attention must be paid to developing principles related to evaluation and assessment of preventive and therapeutic measures after they are adopted and used. Such "post marketing surveillance" is only now being developed for drugs and occurs only sporadically if at all in other areas of health care.

The importance of disseminating research results so that they may be put to use cannot be over stressed. The lag time between the development of new knowledge and its application in practice has been frequently noted. One of the most frequent offenders however, has been the federal government itself. Perhaps a principle should be added which would call for the various arms of HEW itself to communicate better so that research findings may be more effectively applied to its own programs.

Thank you for the opportunity to present these views.

September 1978

CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

Testimony by:

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Physical therapy is both a health care profession and a health care service essential to preventing, reducing, and overcoming problems of physical disability and pain. Attached to our written testimony are summary statements which describe the mission of physical therapy, the characteristics of physical therapy treatment and examination methods; the characteristics of physical therapists, and the characteristics of physical therapy education germane to the focus of this session.

Overview of the Problem

We believe that these summary statements about our profession present an overview of a fairly typical non-physician health care profession in terms of:

1. The uniqueness of content and growth in scope of the profession's practice;

2. The insatiable demands for persons in the profession to provide health care services, to administer or oversee the delivery of those services, and to teach the growing numbers of young persons who seek entry into and are needed by the profession;

3. The relative lack of clinical research evidence to support or justify the methods used by the profession;

4. The relative difficulty of producing enough persons, qualified in both practice and research, who can address the needs for clinical research in the profession; and,

5. The relative difficulty of attracting persons qualified in both practice and research to positions of major responsibility for the clinical research which the profession needs.

As in the several other non-physician health care professions, clinical research in physical therapy is growing in quantity and scope but it is not catching up with the need to validate existing practices, much less the newly developing practices and innovations, in the profession.

The Funding Problem

Our Association is developing a plan to foster clinical research in physical therapy. The final draft of the plan is being prepared now and will be acted upon in November 1978. We are confident that we can implement this plan using our own human and financial resources but we see one obstacle to success: the funding of clinical research in an amount sufficient to make a dent in our clinical research needs.

A higher funding priority should be given to clinical research in physical therapy and the other non-physician health care professions. The health care services provided by these professions are essential, substantial, and generally unique to each profession. Research into these services receives only a fraction of the health research support in this country, chiefly, we believe, for the following reasons:

1. The clinical research problems which need to be addressed in the non-physician health care professions are largely unknown to health researchers outside those professions and receive scant attention from the health research enterprise.

2. The clinical research needs in the non-physician health care professions are overshadowed by the prominence of basic and applied biomedical research; while we agree to the importance of biomedical research and even draw upon such of its findings as are useful to our practice, we do not think it represents the entire continuum of health research as some people are wont to perceive it.

3. The results of clinical research in the non-physician health care professions have little, if any, consequence for the commercial production of drugs and other consumable health products; that is, the economic consequence of this research bears less upon the marketing of health products and more upon the delivery of health services -- a situation which is not conducive to attracting non-governmental funding for research.

We think the public which receives our services and the government which reimburses us for some of our services have a stake in our clinical research. We think the higher funding priority for clinical research in physical therapy and the other non-physician health care professions must come from the federal government.

The Solution

The solution to the problems we identify is not simply one of applying more money. We think certain principles should govern the application of more money to clinical research in the non-physician health care professions. We classify these principles under immediate purposes, long-range purposes, and assurances.

Immediate Purposes

The immediate purposes of funding clinical research in the non-physician health care professions should be to:

1. Support the periodic collection of uniform mass data on patient diagnoses and problems, treatment and examination methods used, frequency and duration of treatment, and patient outcomes, as baseline information for determining clinical research needs and priorities and for identifying useful clinical research hypotheses.

2. Support studies of the reliability and the concurrent and predictive validity of examination methods used and proposed for use in practice.

3. Support studies of the clinical effectiveness of treatment methods used and proposed for use in practice, as well as the conditions under which the effectiveness of the methods varies.

4. Support development of clinical research centers in the non-physician health care professions.

Long-Range Purposes

The long-range purposes of funding clinical research in the non-physician health care professions should be to:

1. Accumulate a basis in clinical research evidence for the treatment and examination methods used in practice.

2. Guide by evidence, rather than by preference or whim, the scope and content of practice and education in the professions, as well as the policies on reimbursement for health care services.

3. Create clinical environments which, both intellectually and financially, will attract and hold non-physician health care professionals who are qualified to perform important, sustained clinical research in their professions.

Assurances

To achieve the immediate and long-range purposes of funding clinical research in the non-physician health care professions, and to effect the application of new knowledge, the following assurances should govern the funding of that research:

1. Restrict the funding of clinical research to applied research in clinical

settings and, where germane to the validity of the research, on subjects who are patients.

2. Allocate a substantial portion of the funding through, or in close cooperation with, the appropriate professional associations.

3. As conditions for their participation, oblige the appropriate professional associations to:

    a. assist in determining the needs and priorities in clinical research germane to their professions

    b. publish widely in the media available to them the findings of funded clinical research

    c. incoporate the pertinent implications of convincing clinical research evidence into the standards of practice of their professions.

# # #

Attachment

ASSOCIATION OF SLEEP DISORDERS CENTERS

EXECUTIVE COMMITTEE

PRESIDENT
William C. Dement, M.D., Ph.D.
Director, Sleep Disorders Clinic and Laboratory
Professor of Psychiatry
Stanford University School of Medicine

VICE PRESIDENT
Elliot D. Weitzman, M.D.
Director, Sleep-Wake Disorders Unit
Professor and Chairman of Neurology
Montefiore Hospital and Medical Center
Albert Einstein College of Medicine

SECRETARY-TREASURER
Thomas Roth, Ph.D.
Co-Director, Sleep Laboratory
Associate Professor of Psychology in the Department of Psychiatry
University of Cincinnati

MEMBERS-AT-LARGE
Peter J. Hauri, Ph.D.
Director, Sleep Clinic
Associate Professor of Psychiatry
Dartmouth Medical School

David J. Kupfer, M.D.
Director of Research
Western Psychiatric Institute and Clinic
Professor of Psychiatry
University of Pittsburgh School of Medicine

October 3, 1978

A Testimony Before the Panel on Clinical Applications
and Health Services Research

I am Dr. Merrill M. Mitler. I represent the Association of Sleep Disorders Centers in the capacity of Secretary-Treasurer (newly elected). Attached to my written statement is a copy of the Association's guidelines for accreditation and other pertinent documents.

The Association represents practitioners of a new and emerging clinical discipline that deals intensively and effectively with the diagnosis and treatment of sleep disorders patients. These practitioners work in about 20 centers across the United States. Most centers are connected with a medical school environment.

We view this conference as an enormous opportunity for health research in general and our field in particular. My testimony reflects the collective experiences I and my colleagues have had in conducting sleep research and dealing with sleep disorders patients. I hope that my comments will be considered within the excellent framework of guidelines and principles associated with this conference.

The field of sleep disorders medicine has come into being in response to an overwhelming clinical need and many basic researchers are now inundated with clinical responsibilities. However, now we face almost insurmountable problems in making current findings available and in making further advances in our knowledge.

What is the scope of the clinical need?

- Some 50 million Americans have complaints about the quality of their sleep and/or the effectiveness of their functioning during wakefulness. Thus, 50 million are at risk for a potentially life-threatening sleep disorder.
- The number of daily doses of drugs ingested for such sleep-wake complaints (including caffeine and alcohol) almost certainly exceeds the 50 million figure.
- On 3.5% of all patient visits to physicians a potent hypnotic is prescribed. The total in 1976 for such prescriptions was 7.3 million.
- Well-over 250,000 Americans have documented, life-threatening sleep-wake problems like narcolepsy and sleep apnea. This figure does not include victims of Sudden Infant Death Syndrome which is almost certainly related to sleep. The additional number of potentially serious problems is as yet unstudied.
- There is a clear relationship, established by the massive, longitudinal survey of the American Cancer Society, between reported sleep time and mortality.
- Very serious sleep-wake problems exist in the elderly who have age-related difficulty with sleep. Such patients often receive inadequate and/or risk-laden chemotherapy aimed at improving their sleep.

What is the scope of support for sleep disorders by organized medicine and the Federal Government?

- Not one medical school provides adequate education about sleep disorders, sleeping pills, and stimulants.
- The various medical insurance plans have no clear policy concerning sleep disorders and seriously ill patients are not universally covered.

- Not one Federally supported trial of a hyprotic drug has ever been completed.
- At this time, not one Federal dollar is being spent for research on narcolepsy or the betterment of the daily existence of narcoleptic patients.

Nevertheless, by dint of very dedicated effort, sleep researchers have amassed a significant body of scientific knowledge about sleep disorders that could be applied immediately on a national level. Such knowledge could save literally thousands of lives. Most of this clinical knowledge has been accumulated in the past decade. Furthermore, the technology exists to make additional advances very quickly. But the logical progression from basic research to effective clinical application has essentially been blocked for sleep research.

The community of sleep researchers and sleep disorder practitioners find that the major obstacles to making full use of the knowledge in this health care are as follows:

1. The total lack of specific representation at the Federal level.
   - As far as we can tell, with the exception of Sudden Infant Death Syndrome, not one Institute in either ADAMHA or NIH has specific priority for sleep disorders.
   - It is amazing that the NINCDS does not actively encourage research on narcolepsy.
   - It is amazing that FDA, NIDA, and NIMH have not supported a single study that defined hypnotic efficacy.
   - It is amazing that no person in HEW has effectively noticed the complete lack of sleep disorders training in our medical schools.
2. Another basic obstacle is that our field deals with the totality of human function during sleep. As such, it is an entirely interdisciplinary field. As has been said here before, such interdisciplinary fields fit nowhere in the present structures for administering educational and research funds.
   - We heartily support and applaude those aspects of the principles in Clinical Applications and Health

Services Research that approve the support of problem-oriented health care research.

- We totally agree that some supra-institute body such as the National Academy of Science, the Administrator of ADAMHA, or the Director of NIH should serve to facilitate new and emerging interdisciplinary fields.

3. Another major obstacle has been the lack of support for training physicians and health care professionals in the diagnosis and management of sleep disorders. It has been virtually impossible to develop new sleep disorders centers because of a lack of trained personnel.
   - We endorse the principles that call for the systematic desemination of research results and related data for concensus development so that advances in knowledge are applied to the health care system as promptly and effectively as possible.
   - We assume that these principles apply to the results and data of our field that promise so much for the diagnostic and treatment techniques of sleep disorders medicine.
4. The last obstacle that I wish to mention is the functional lack of peer review for research proposals involving sleep and wakefulness.
   - Established scientists from other fields are asked to critique proposals dealing with sleep and wakefulness and asked to share their field's limited research funds with the new and emerging fields of sleep research and sleep disorders medicine.
   - We heartily endorse the principle that health care research should be evaluated for scientific content and validity by peer review or by the technical concensus approach. However, sleep disorders research must have guarantees of genuine peer review for their proposals -- not review by those whom entrenched disciplines designate as informed peers.

- The practitioners and investigators in our area must play a major role in establishing an adequate peer review system for our work.

As the final portion of my testimony, I want to point out that the Association of Sleep Disorders Centers urges this panel to support setting health research expenditures in some reasonable proportion with the following factors:

- risk to life and property.
- prevalence to the disorder (specifically the insomnias and the hypersomnias).
- recent research successes in the field.

Yours truly,

Merrill M. Mitler

Merrill M. Mitler, Ph.D.
Secretary-Treasurer, Association of
Sleep Disorders Centers
Chief, Laboratory of Electrophysiology
State University of New York at Stony Brook

PRESENTER: Carol A. Lindeman, RN, PhD
Dean, School of Nursing
University of Oregon Health Sciences Center
Portland, Oregon 97201

REPRESENTING: American Association of Colleges of Nursing
Sigma Theta Tau, National Honor Society of Nursing

PANEL: Clinical Applications and Health Services Research

My name is Carol Lindeman, Dean, School of Nursing, University of Oregon Health Sciences Center in Portland, Oregon. I am representing the American Association of Colleges of Nursing and Sigma Theta Tau, National Honor Society of Nursing.

Although I am an active member of the research community and would like to provide testimony that would not only protect but enlarge my share of the research dollar, that is not my focus. Instead I have chosen to speak from the perspective of the health care recipient. For to me, it is impact at that level that makes the aspect of research effort that this panel is addressing, worthwhile.

With this perspective, there are four major categories of research effort that emerge:

1. Research that links process to outcome
2. Research that explores alternate delivery systems to ascertain that the public can indeed receive care
3. Research that deals with consumer and provider response to care
4. Research that deals with feedback to the professionals to insure that new information will be used in practice

Without research monies to support each and all of these efforts, the total effect is compromised.

Experience over the years shows that improvement in the quality of life can only come when scientists from several disciplines attack a problem. Greater improvement in the quality of life has been made through agriculture, economists and housing officials than from most basic medical research. Child abuse is not only a medical problem. Abortion is not only a legal problem. Care of the elderly is not only a nursing problem. Mental retardation is not only an educational problem. Resolution of problems such as these requires a multidisciplinary approach.

I, therefore, urge the panel to include an interdisciplinary, behavioral focus as a basic principle for research related to clinical applications and health services. This inclusion is not meant to exclude basic medical research but to be an addition to that focus.

It is also evident that not all health care activities have a basic science origin. Relating care and cure processes to outcome is a science in itself. It is applied only in the sense that it takes place in the real world -- not that it is a direct application of knowledge generated from basic science research. Those health professionals concerned with providing care and making the system work should be valued in terms of allocation of research dollars to the same extent the health professionals concerned with basic science and cure research are valued.

Examples of this type of research include:

-Ann Marie Jane, respiratory care specialist at Cook County Hospital in Chicago. Ms. Jane, using an alternate delivery method, helped nine of her eleven patients avoid hospitalization for a one year period.

-My own research on care of the presurgical patient showed a significant decrease in length of hospital stay for patients receiving structured preoperative teaching. The research was replicated in Canada with the same general conclusion but in addition showed people returned to work in a significantly shorter time. Cost savings and improved quality of life were demonstrated.

I also urge a targeted approach with multi-year funding as the logical way to improve health care through research. In 1974, a Delphi Survey of Clinical Nursing Research Priorities was conducted using a large national group of experts. Three years later these priorities remain an unanswered research issue. They deal with basic care issues -- stress, pain, dying, self-care. Targeted areas for funding should no longer be tied to pathology or disease categories but these more basic universal concerns of the sick and the well.

In summary, the research dollar must stretch across all components of a health care model. This requires behavioral as well as biological research. It requires a multidisciplinary approach. New research professionals must be allowed to contribute.

Testimony Presented to the Panel on Clinical Applications and Health Service Research

Dr. Henry H. Work, Deputy Medical Director
American Psychiatric Association

National Conference on Health
Research Principles

October 3, 1978

Our formal testimony has been prepared by Dr. John Davis and was to be offered by him; unfortunately this has not worked out. I would like to speak for our organization and the concerns that we have, and the type of interests that are constantly changing.

You heard this morning from Dr. Miller of the State Mental Health Directors, and in specific, his concerns mirror ours. Our concerns, in general, are more broad with a massive concern about health services and the research necessary for carrying out these health services. The number of patients who are mentally ill or emotionally disturbed seems not to decrease. If anything it continues to mount. The cost of care of patients, despite changing methods in care, has not decreased, and again may be increasing. If we lump in the care of the mentally ill, those who suffer from various illness related to alcoholism, and those who are involved in drug abuse problems, the total numbers increase massively. Rather belatedly, our organization has taken a major interest and concern in the chronically ill patient. This is long overdue and what it has focused on is two other interests of ours, namely those of hospital care vs. community care, and treatment vs. prevention.

You heard this morning that the Research Task Panel of the President's Commission on Mental Health had pointed out some of the basic facts about which we are concerned: mental health research has stagnated, that it is down 20 percent from 1969, and the recommendations of that panel are moderately staggering, and yet, we feel, appropriate. Thirty million for the NIMH, nine million for NIDA, and nine million for the Alcohol Institute.

I mentioned the two major concerns that we have had for many years: most recently, our concern about the hospitalized patient who has been moved out for various political reasons into the communities, and of whose care we are concerned. We are only beginning to get research data as to whether or not people who are dumped out of the hospitals are adequately or inadequately cared for in the community. This is a crying need in the health services area.

A more long-lasting concern of our organization has been where to put the funds in the general split between treatment and prevention. We are aware that more recently our interest in brain chemistry has altered, and hopefully increased, our knowledge of treatment. We have no such optimism about prevention, unless it is linked to other efforts such as we have heard all morning, efforts in the primary care field, efforts in the education of other caretakers for our patients. What I guess we are lacking is research that will help us make that education more valuable, more understandable, and more useful to everyone concerned.

Thank you.

My name is Robert Rice, and I am representing Family Service Association of America, an association of nearly 300 family service agencies throughout North America. Perhaps with that introduction, you can anticipate that I wish to speak to you about families and how they are related to clinical applications and health services research.

It is not difficult to find references to the relationship of family and health. Many writers have observed that characteristics of family are as significant a predictor of health and illness as any. Many commentators on health care, within the medical profession, social work, nursing, health planning, or allied health professions speak of involving the family in health care as an effective measure. Observations of the power of families in their members' lives are so pervasive in so many disciplines that some observers have reformulated ideas about families, seeing them as care-giving institutions in their own right. Considered in this light, families themselves are the primary means by which health is protected, illness is prevented, or care is given when illness strikes. Medical regimens may be supported or sabotaged by family behavior. In other words, families can be perceived as direct health treatment facilities, while health professionals must often be only indirect influences upon primary care provided by families.

It is remarkable, then, that there is so little research about how the family may be enriched in its mediation and implementation of health care. Perhaps this has to do with our tendency to identify families with maternal parent-child relationships, rather than as the pervasive and powerful systems of influence throughout life that they are. We continue to conceptualize that professionals directly care for patients, whereas they often may only influence what actually occurs. Moreover, very little research has developed showing how families may be used in clinical applications as primary care-givers, or how families may be encouraged as preventive health resources. Organizationally, services focussing on family life, such as those our members provide, tend to be disconnected from health delivery services, and we all lose opportunities for synergistic linkage.

I notice that materials developed by NIH to date speak of provision of health services in broad terms, and emphasize prevention and community care. Very little of the preliminary material for this national conference mentions the issue of family mediation of health services, however. Probably this is a reflection of the state of our knowledge, and the inadequacy of our way of perceiving how professionals affect human beings. It would seem entirely consistent with the preliminary directions of the Health Research Principles to suggest further rigorous research into how families themselves may be empowered to fulfill their roles as a primary health institution.

I'm most pleased to have the opportunity to make this statement so directly.

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THE NEW YORK HOSPITAL-CORNELL MEDICAL CENTER

DEPARTMENT OF PEDIATRICS
DIVISION OF PEDIATRIC ENDOCRINOLOGY

October 3, 1978

To: National Conference on Health Research Principles

From: Dr. Maria New

READ AS TESTIMONY BEFORE THE PANEL ON
CLINICAL APPLICATIONS & HEALTH SERVICES RESEARCH

The Council of the Society of Program Directors of the Clinical Research Centers met on May 2, 1978. At this meeting, there was concern expressed about the new clinical investigators and the number of research grants being awarded by the National Institutes of Health in clinical investigation. Since the Clinical Research Center's program will depend on the generation of new clinical investigators being developed, various proposals were considered for mending this undesirable situation.

The evidence indicates that the number of program projects and the number of individual grants to new investigators and established investigators holding M.D. degrees has decreased while the investigators with Ph.D.s receiving research grants has increased. This trend, a reversal of the M.D./Ph.D ratio has occurred during the period of 1966 to 1976. Further, it was observed that the age at which M.D.s become new principal investigators on research is 38, while that of Ph.Ds is 34.

Discussion centered on the reasons for the decrease in the number of M.D.s entering clinical investigation or even academic medicine. Factors considered important were: 1) The economic factor; it is difficult for a physician at the age of 38 to take the cut in salary necessary to undergo a training period in clinical investigation. 2) The payback system is another deterrent to entering the field of clinical investigation. 3) There seems to be little emphasis at the medical school level in making research a desirable area of endeavor. 4) It takes a long time for a clinical investigator to mature so that his work becomes fruitful and productive as evidenced by publications or other training research grant support.

Several proposals to repair this situation were considered. I shall enumerate them here with some discussion. 1) To request support from the General Clinical Research Centers Branch of the Division of Research Resources for Clinical Investigation, to ask Dr. Bowery to encourage the medical schools to distribute the GRS support for training young medical students in clinical investigation such as summer fellowships. 2) To request in a similar manner that the minority training program money be distributed to encourage young investigators to enter clinical investigation by offering them summer fellowships on CRCs. 3) To consider reallocating the CRCs budget so as to include some support for young clinical investigators in addition to the CAP program. 4) To support the proposal by Dr. Helen Ranney to establish the Hubert Humphrey Scholarship Program with the proviso that that money include training for clinical investigators.

The entire Council of the Society for Program Directors of the CRCs felt that there was indeed a problem in developing clinical investigators. It was pointed out by Dr. Califano listed as one of the five goals for the next five years the support of young investigators. We as a group feel that young investigators should become experienced in clinical investigation. The CAP program has been an emminent success. We need other programs like it. The development of young investigators in clinical investigation is seminal to the advance of human biology and better health.

Maria New

National Conference on Health Research Principles

October 3-4, 1978

Comments By

Robert L. Berg, M.D.

University of Rochester

Representing

Association of Teachers of Preventive Medicine

American College of Preventive Medicine

Clinical Applications and Health Services Research

Clinical applications is part and parcel of health services research, for clinical applications implies that there is knowledge to be transferred, and health services research shows how to do it:

- Does it work? Epidemiologic and statistical skills are needed in combination with clinical skills to evaluate new forms of therapy and management.

- Is it worth doing? Economics and the derived methods used in systems analysis, especially cost benefit analysis, are the basic tools needed, building on the data derived from epidemiology and statistics.

- How can it be implemented? Behavioral sciences are the necessary disciplines for this purpose. This includes approaches to acceptability and compliance by providers and consumers which are closely related to continuing medical education and public health education.

It is astonishing that so little of the health research dollar has gone towards these goals. A larger proportion is urgently needed in order to achieve savings in health care and to improve the health status of the population. It is irrational to spend a very large amount of money on basic research and development when the application of this knowledge is so faulty.

Federal health policy for research needs to be adjusted to strengthen clinical application and health services research in medical schools where a majority of basic work is done;

- To increase the bridging that already exists between basic science departments and clinical departments.

- To capitalize on the association with medical student and resident teaching so that they will learn to carry the model with them into practice.

- To exploit departments or units of preventive medicine and community health where the expertise in epidemiology, biostatistics, and behavioral science is concentrated.

The following statements provide useful extensions to the list of health research principles already circulated.

- Principle -- Technology transfer will never get off the ground, unless as in the moonshot, there is intimate coordination between experts.

  - Basic scientists, clinical investigators, and health care researchers can best evolve coordinated clinical applications in the medical school setting. Such coordination is essential to answer the questions: Will it work; Is it worth doing?

  - Clinical applications require patients. As in Willie Sutton's Law, this research goes to health care institutions, where the patient is.

  - Basic medical research will have the greatest opportunity for application with support from epidemiologists, statisticians, and behavioral scientists; especially from adequately funded departments of preventive medicine and community health.

- Principle -- Technology transfer must cast a wide net to capture the generalist, as well as bait a sharp hook for the specialist.

  - Most health care delivery is general and comprehensive, not subspecialty oriented. New knowledge must develop special strategies to reach the generalist, especially to answer the question: How can it be implemented?

  - Teaching and medical care ties for generalists should be strengthened to teaching hospitals, so that technology transfer flows easily as a part of patient care.

- Principle -- A miasma of health services research should envelop teaching hospitals.

  - The leading fringe of knowledge in health services should surround the medical student and resident. They should participate in it, feel it in their bones.

  - The interaction of epidemiologists, statisticians, and behavioral scientists should extend into all clinical departments so that critical evaluation of new clinical applications becomes contagious and infects all students, residents and faculty.

Tibor J. Greenwalt, M.D.
Senior Scientific Advisor
American Red Cross

Comment for Panel 2 -- Clinical Applications and Health Services Research

The Red Cross Blood Services collects and processes into components about 50 percent of the blood used in this country. We are keenly interested in the Clinical Application of the fruits of Health Services Research because they are essential for the delivery of health care. Modern blood banking and transfusion service is an integral part of medical practice and is often called upon to support the most radical new surgical and medical developments.

We must have data and the skills to plan for the future needs created by new developments. To do this effectively blood banking organizations must be involved at an early phase in the planning and decision process.

Without the development of the needed data, reasonable and acceptable regulation and the necessary educational activities cannot be performed.

Mechanisms are needed to evaluate new procedures, new equipment, new tests and new reagents in order to establish their safety, effectiveness and proper place in medical practice and also to prevent the distribution of products and the dissemination of practices which have not been shown to be effective or needed. At the same time support should be available to develop and improve products, equipment, methods and materials which are neglected because of the absence of a large enough market for profitability to the commercial sector.

The importance of applying the skills available in the fields of management research, statistical analysis, public information and education, communications and transportation, cannot be overemphasized. Developmental work on the application of these disciplines to the delivery of health care has to be encouraged and supported.

To sum up, Clinical Application of Health Services Research needs:

Structure(s) to continually review the perspectives and to order the priorities.

The data base to make this possible.

A mechanism to select the best methods to implement the selected priority objectives.

A continuing overview of progress with sufficient flexibility to adapt to changing needs.

The means to keep the public and the professionals adequately informed and to promote, collect, collate and evaluate the feedback.

Funds to support these activities.

October 4, 1978

Dr. F. M. Parkins, Assoc. Dean
College of Dentistry
University of Iowa
Iowa City, Iowa 52240

STATEMENT OF
THE AMERICAN ACADEMY OF PEDODONTICS
AND
AMERICAN SOCIETY OF DENTISTRY FOR CHILDREN
BEFORE THE
PANEL ON CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH
OF THE
NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

OCTOBER 3, 1978

FREDERICK M. PARKINS, D.D.S., M.S.D., PH.D.

I AM DR. FREDERICK PARKINS, HERE TODAY REPRESENTING THE AMERICAN ACADEMY OF PEDODONTICS AND THE AMERICAN SOCIETY OF DENTISTRY FOR CHILDREN. THESE GROUPS COMPRISE THE SPECIALTY AND GENERAL DENTAL ORGANIZATIONS THAT EXCLUSIVELY CONCERN THEMSELVES WITH CHILD DENTAL HEALTH.

DENTAL CARIES AND PERIODONTAL DISEASE ARE PROGRESSIVE CONDITIONS WHICH BEGIN DURING CHILDHOOD. BEFORE REACHING THE AGE OF 18 THE MAJORITY OF THOSE ORAL TISSUES LIKELY TO BECOME PATHOLOGIC HAVE ALREADY EXPERIENCED INITIAL DAMAGE. OVER 95% OF THE POPULATION SUFFER FROM DENTAL DISEASES. YET MOST DENTAL DISEASE IS PREVENTABLE WITH SUITABLE CARE STARTED DURING EARLY CHILDHOOD.

WE FEEL THAT DENTAL RESEARCH HAS NOT RECEIVED ITS FAIR SHARE OF SUPPORT. DENTAL HEALTH CARE NOW REQUIRES 6% OF ALL HEALTH EXPENDITURES, WHILE DENTAL RESEARCH RECEIVES LESS THAN 1% OF HEW'S DEPARTMENTAL RESEARCH FUNDS. AS OTHER INITIATIVES HAVE GROWN IN RECENT YEARS THERE HAS NOT BEEN A PROPORTIONATE INCREASE IN SUPPORT FOR DENTAL research. In constant dollars there appears to have been an actual loss of funding.

We share the belief of all organized dentistry that improved dental health must begin with the child. Dental conditions are among the five leading causes for visits to physicians by children. Dental decay, with its associated pain, infection and debilitation is a leading cause of morbidity statistics for children. There are life-threatening consequences to dental disease when accompanying systemic conditions such as hemophelia and congenital heart disease. Yet little systematic effort is being made to apply our present fundamental knowledge to the eradication of dental disease in children.

While the National Institute for Dental Research remains one of the smallest NIH institutes, it has made outstanding contributions to fundamental research. It is in the application to the dental care system of new knowledge and health services research that the Department is most negligent.

A unifying focus for applied research and health services research for the treatment and prevention of dental diseases does not exist. The Division of Dentistry, Bureau of Health Manpower was just subjected to a drastic personnel cut and branch dismemberment. The Dental Health Center in San Francisco has been closed, the Dental Manpower Center in Louisville has been closed. The Center for Disease Control (CDC) was assigned the responsibility for preventive dental initiatives. This new obligation was assumed without any increase in budget. At present, one dentist and one public health advisor administer for CDC what could only kindly be called even a toekn program to prevent dental diseases across the nation.

The development of preventive dental programs for preschool children and optimal use of school settings for the prevention of dental diseases should be encouraged. Methods for arriving at a technical consensus for newly developed dental materials accompanied by programs of continuing education to disseminate the outcomes need to be stimulated. Projects for curricular innovation in dental education leading to preventive oriented graduates and behavioral studies leading to reduced dental patient anxiety and increased utilization of self-administered preventive practices ought to be initiated. These are but a few of the promising areas which are now being largely ignored.

Dental diseases are preventable and correctable. Dental care has been shown to improve health status. The dental delivery systems have shown an exemplary capacity for cost containment with fee increases well below the cost increases for all services. This is a direct outcome of increased efficiency brought about by earlier federal programs in dental auxiliary utilization. However, less than half of the population now receives regular dental care. Almost half of our children do not reach adulthood before the loss of diseased permanent teeth. Further development of improved dental care and dental care system delivery, especially for children, deserves a specific place in the formation of the Nation's Health Research Principles and a prominent place in any multi-year research strategy.

Mr. Chairman, my name is John Hein, Director of Forsyth Dental Center in Boston, and today I represent the American Association for Dental Research. The American Association of Dental Schools and their representative Dr. Ian MacKenzie, as well as the American Dental Association and their representative, Dr. Irwin Mandel, are in support of our prepared statement.

We have chosen to testify on Clinical Applications and Health Services Research rather than Fundamental Research because we perceive a need for clarity and direction and coordination of activity in this area of research, especially in dental research.

The American Association for Dental Research is in general agreement with the health research principles, as presented for our consideration, with the understanding that all disease oriented research can not be similarly performed and administered. We feel that research directed toward oral disease needs special attention and we hope that our comments today will embellish this special consideration.

We in dental research are in great need of institutional training programs that prepare those with dental backgrounds in fundamental, clinical and health services research. Unless these programs are quickly implemented and supported by stable long-term commitments, it will be difficult to attract, train, and maintain competent researchers and our mission will be jeopardized. Furthermore, clinical and health services research activity in dentistry is disproportionately lower than fundamental dental research activity. Additional support for clinical research activity should be developed, while maintaining appropriate support for fundamental research activity to flourish. Dental institutions have not had adequate encouragement or incentives to become actively involved. Consequently, those dental scientists who have performed or who are now performing health services research are accorded less status within the research community.

The AADR recommends that an intensive study related to dental research be devoted to identify those factors which facilitate and foster the movement of new knowledge toward practical application. We believe that such a review should not only analyze this process as it takes place in academic, government, and not for profit research institutions, but in industrial research environments as well since the latter often deal with the final stages in bringing practical applications to the public. We believe that the criterion of scientific excellence applies to the entire research continuum spanning from basic biological research, disease targeted mission oriented research, clinical investigations and large scale programs of implementation. Therefore, it is important to identify and foster those factors which will attract outstanding individuals to every stage of research enterprise. The AADR believes that such a review will reveal that there are at present decreasing incentives as one comes closer to the application. Specific correlated disincentives are: 1) the erroneous belief that there is less opportunity or need for creativity in applied clinical and health sciences research 2) a predominance of contract support for such research and 3) the sporadic nature of support for such research.

The American Association for Dental Research supports the principle that investigator-initiated fundamental research support should provide for stability to the overall effort. In this regard we would also endorse greater use of investigator-initiated grants in the areas of clinical and health services research. We are in agreement and endorse the principle that there must be enough leeway throughout the system for the development into new areas of research that will ultimately benefit the public.

The National Institutes of Dental Research supports most of the basic and disease oriented research related to dentistry. It has to some extent become involved in implementation of derived technology by supporting a school based fluoride mouth rinse program. However, there are and should be limitations to the mission of NIDR. Thus, we endorse the principle that encourages the development of an adequate knowledge base and it's systematic and coordinated development by other health related agencies.

Futhermore,the reorganization and reduction in manpower of the Division of Dentistry,which formerly supported much clinical and health services research has seriously reduced dental research potential. Also, the Center for Disease Control has only limited resources in order to carry out it's dental prevention and control initiatives.

It should be now be obvious that a better coordinated long range policy and management structure is necessary to guide the future direction for dental health research. We would recommend the establishment of a study for the Secretary or a Presidential Commission to review and recommend a better coordinated framework for development and implementation of policies which will improve the ability of the dental research community to serve national goals related to oral health.

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
NATIONAL EMS SYMPOSIUM
MINNEAPOLIS, MINNESOTA
DECEMBER 13-15, 1977

BEHAVIORAL WORKSHOP

BRITA O'CARROLL - NCTCOG EMS PROJECT, DALLAS

PROBLEM

Behavioral (including substance abuse problems) critical care has not received the same degree of urgency for emergency medical care development as has the six other defined areas *. The prioritization, especially for pre-hospital and emergency department triage, is for below documented need for accurate dispatching, critical care plans, and protocols, and manpower training.

RATIONALE FOR THIS PROBLEM:

- Mental health treatment is not as clearly defined as other critical care areas because of the diversity of behavioral emergencies, and their causes, diagnosis and definitive treatment approaches.

- Emergency medical services emergency department personnel tend to be Type A personalities, who prefer to have visable and immediate diagnosis and treatment results. Behavioral problems (including substance misuse), are usually long-term and frustrating, requiring a great deal of delay of gratification, except in instances where definitive physical medical aid is also required.

- The myriad of laws which affect this segment of health care in so many ways and areas of concern, make it very difficult to approach commonalities that can be applied on a widespread basis. Further, these laws frequently are so complicated, that only a few know the extent of their mandate in a day-to-day functional treatment manner.

* Critical care areas as defined by EMS System: Major shock/trauma; cardiac; high risk infant/neonatal; burns; spinal cord injuries; and poison, smoke and spider bite control.

- Many people providing emergency medical services care are not particularly interested in behavioral problems and tend to view them as social rather than medical health problems. Yet, N.I.M.H. states that 42% of those treated for emotional problems have related medical problems.

- When preparing disaster plans and conducting subsequent drills, behaviorally related problems take a place far behind physical injury or illness, with the exception of the hysteriac walking around getting in the way. Although behavioral crises during and after a disaster comprise a significant amount of emergency services needs - and are the most difficult for untrained or inexperienced personnel to deal with - physical injury and disaster logistics receive the primary focus in planning and care provisions.

CONSIDERATIONS REGARDING PRESENT STATUS OF BEHAVIORAL CRITICAL CARE

- The psychiatrists have not addressed this aspect of mental health in much of an organized or enthusiastic manner. Thus, the EMS System should and can take the organizational lead for pre-hospital treatment and emergency department triage related to critical care for behavioral medical and social services. These activities would be collaborated with the mental health specialists.

- Behavioral critical care plans are sorely neglected, and are as important as the other six critical care areas.

* - There has not been developed to any organized and thorough degree, a real working protocol/critical care plan process for behavioral emergencies (to the extent as seen in the other six critical care areas).

* - The preliminary report to the President from the President's Commission on Mental Health, September 1, 1977:

    - does not really address the pre-hospital/emergency department needs for treatment of behavioral patients except with reference to "the need to view mental health problems in terms of duration and intensity of care and assistance people need..."

- In the late 1950's the direct cost of mental illness was estimated to be $1.7 billion; and, this does not take into account the cost of pre-hospital emergency care in the area of use, or misuse/abuse of the EMS system.*

- The direction of mental health treatment is towards non-institutional community care. So, we are likely to see an increase in emergency behavioral calls, especially in the areas described in the President's report.

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* President's Commission on Mental Health,
September, 1977.

  - 8.1 million of the 54 million children and youth of school age (15% of that population) need psychological help;
  - There are 200,000 cases of child abuse reported a year, and people in the field feel the real number is at least 10 times that figure;
  - There is an alarming increase in adolescent suicides, depression, alcoholism.

- Data on the number of either precipitating or major behavioral factors related to emergency calls is presently impossible to gather in a clear, precise form, because the variables and parameters are not clear-cut; i. e., run reports are not set up to clearly determine all behavioral emergencies. Many medical categories on run reports suggest major behavioral components and all have a degree, such as:

  - Suicide
  - Rape
  - Physical abuse, assault and battery
  - Fainting
  - Hysteria
  - Over-dose
  - Alcohol related, D.T.s
  - Driving while intoxicated
  - Perforated ulcers
  - Asthma
  - Coronaries
  - Gun shot wounds, stabbings
  - Auto accidents
  - Trauma
  - Other accidents, etc., etc., etc.

✳ - There is a need for the development of better baseline scientific data which can be turned into usable information about:

  - emergency behavioral patient groups
  - linkages between the pre-hospital and Emergency Department areas to definitive and/or long-term care
  - community profiles for emergency behavioral groups
  - efficacy of this aspect of EMT/Paramedic training and public safety agency training for:
    - day-to-day problems
    - disasters
    - efficacy of present public education and information programs related to mental health

- Informally, peole involved in day-to-day EMS ambulance units, feel at least 40-50% of their runs have a precipitating or major behavioral factor.

Perhaps, one of the most important reasons for health care providers and system managers alike, to feel the urgency for the development of organized and thorough pre-hospital and emergency department critical care plans and protocols, is the potential for decreasing system misuse or abuse and increasing appropriate use:

- From the patient's aspect of trying to get into the system for appropriate emergency or immediate care and then continuing help in the best way, and at the best time;
- From the provider's aspect of giving proper immediate emergency care, and thus channeling the patient into the best continuum of care;
- From the total health delivery system and the mental health and EMS sub-system's perspective, decreasing the "revolving door" syndrome (which is expensive to the system and the patient), and which often circles the patient around and gets him essentially nowhere but frustrated.
- We do not have a good enough handle on the number of emergency behavioral patients which could be significantly reduced by improved pre-hospital and ED critical care protocols and triage:
    - morbidity
    - mortality
    - rehabilitation
- IF WE COULD REDUCE THE NUMBER OF EITHER NON-EMERGENCY OR REPEATED BEHAVIORALLY PRECIPITATED CALLS AND RUNS BY 25% (THROUGH PROVIDING APPROPRIATE PROTOCOLS FOR PRE-HOSPITAL CARE AND EMERGENCY TRIAGE), IT COULD HAVE A TREMENDOUS IMPACT ON EMS SYSTEM ABUSE, MISUSE, MORALE AND MANAGEMENT PROBLEMS:
    - providers
    - patients
    - economics
- On-line EMS staff (pre-hospital and emergency department) are presently not only lacking in triage and treatment skills, they presently have little opportunity to learn positive ways to cope with:
    - Their feelings about behavioral problems - including identification with patients or situations.
    - Interviewing and communicating.
    - Sorting verbal and non-verbal data being transmitted by the patient, and transmitting this information to physicians and reporting forms.
    - Getting physicians to take staff psychiatric observations as seriously as they take "medical" problems.
    - Many physicians will not accept nurse intake information.

  - Small emergency departments usually cannot handle a bumptuous or rowdy patient.
  - Hospital social workers frequently do not have a working knowledge of or contacts with community mental health, drug or alcohol facilities and agencies.

- (Emergency Department) Medical control is generally weak in behavioral crises; except in large teaching facilities. Even if the physician is excellent in providing mental health care, he rarely knows and understands the intricacies of all the legal mandates or options available to himself or the patient for the most suitable evaluation and treatment, i. e., the complexity and confusion of Florida's Baker & Myers Acts, or the multiple community agencies available for referral.

- Physical medicine staff are often more cursory about behavioral diagnosis than they are about "medical" problems. And, even if they are careful, their psychiatric training for emergencies is all too often inadequate. Further, frequently many "medical" problems are incorrectly given mental health labels, i. e., diabetic acidosis, topical poisonings (fertilizers, etc.), epilepsy and so on, are labeled "psychotic."

- Incorrect psychiatric or medical diagnoses frequently are put in the status of "chronic undifferentiated schizophrenia" or "personality disorders", a label which once on a medical chart, regardless of its inappropriateness cannot be shaken easily.

- Treating people as "mental" problems, rather than medical emergencies, and then diagnosing the same way, tends to create a self-fulfilling prophecy by staff and patient alike. Patients cannot be treated properly by diagnosing first and evaluating second.

- Pre-hospital and emergency department staff greatly resent "revolving door nuts" who take away their time from "real" emergencies. Even the one-time mental health crisis patient is treated with the attitude that he or she is joining the "revolving door brigade."

- There is still a stigma attached to behavioral problems which carries over into rejecting diagnosis and definitive treatment by both the physician and patient - especially if he or she is white, upper middle class and prominent in the community.

- Even in a clear medical problem, a patient's anxious behavior can increase the difficulty of medical treatment and subsequent success.

- There is a great deal of concern about what to do with voluntary and involuntary patients. We are speaking of emergency situations, and while the patient is in the ambulance:

  - At the time of pre-hospital crisis, voluntary/involuntary may not be the issue.

  - Diagnosis is not going to be made until he is seen by the physician in emergency room or at a later time. Treatment is usually palliative until he reaches the facility.

  - If he is a danger to himself or the community, he is involuntary at the time of crisis. Continuing involuntary treatment is not determined during the pre-hospital period, but via triage, evaluation and definitive treatment.

- Although EMTs, Paramedics and other Public Safety personnel are the most immediate to reach 'on the street' emergencies, they probably have the fewest concrete skills. Many police officers have suggested classes for handling behavioral emergencies, including family disturbances/free-for-alls; and especially physical abuse.

- Public Safety agencies are often unsure of how to deal with behavioral problems, except for finding out the fastest way to get rid of them.

- EMT and Paramedic training is essentially medically/physically task oriented because of all the dexterity skills they should and need to initially learn. Yet, nearly all of the rescue services in our region indicate a great need to learn specific techniques in the behavioral aspect of care. It is amazing to learn the number of health care providers who are unaware that many treatment techniques have even been developed and are being used for behavioral crisis.

- Paramedical personnel feel very inadequate with behavioral emergencies, especially in the areas of;
  - overdose
  - overdose
  - rape
  - wife and child abuse
  - suicide attempts
  - disasters

MAJOR OBJECTIVES TO BE DEALT WITH IN BEHAVIORAL CRITICAL CARE PLANNING AND TREATMENT

1) To develop, test and implement realistic behavioral (including substance abuse) critical care plans, protocols, and triage mechanisms for the pre-hospital and emergency department areas of care, and also

   - Assessing the feasibility of adapting established techniques presently being used in drug and alcohol treatment.

2) To develop more clearly defined data criteria in the identification of precipitating or major behavioral factors in emergency health situations.

3) To gather baseline data for infomation specifically about:

   - What percentage and kinds of emergency calls and runs have major behavioral factors;
   - Demographic and socio-economic information related to these requests and runs;
   - Which of the requests and runs are repeated because of system misuse and/or abuse by either the patient or providers.

4) To develop alternatives for improving the continuum of behavioral patient care; decreasing EMS system misuse and/or abuse; and decreasing the patient 'revolving door' syndrome, including:

   - Implementation and evaluation of behavioral critical care plans, protocols, facility categorization and transfer coordination.
   - Assessing the relationship between emergency care and treatment, and the causes of EMS system misuse or abuse and system management problems (i. e., morale, public complaints, etc.).
   - Methods to improve health system linkages through better interdisciplinary coordination:

     - Emergency Care
     - Treating emotional components of the other critical care areas, especially burns, trauma, cardiac, spinal cord injuries and poisonings.
     - Non-emergency care
     - Continued primary care
     - Follow-through
     - Patient tracer studies

5) To develop improved training and education methods for EMS manpower in order to:

   - better cope with behavioral emergencies;
   - better cope with the high stress levels in their employment to help improve performance and decrease high personnel turnover and divorce rates.

6) To develop and test appropriate evaluation methods for emergency behavioral care.

7) Think about:

   Aside from a physical medical problem, diagnosis may not be as important in the pre-hospital phase as is the severity level of patient disability.

   - Protocols may have to deal with the level of observed behaviors rather than specific diagnosis. This would then cut across all the diagnostic areas, and deal with the present crisis being exhibited.

8) To encourage funding agencies in bringing closer together the research and service delivery priorities so applied research can be more relevant and appropriate.

A. Everette James, Jr., SCM, JD, M.D.
For Panel 2

STATEMENT OF SOCIETY OF CHAIRMEN OF ACADEMIC RADIOLOGY DEPARTMENTS

The discipline of Radiology & Radiological Sciences is particularly challenged by the types of decisions that are before us at the present moment. As a specialty we embrace not only the basic sciences characteristically applied to medicine but to the physical sciences as well. In the health care system, we function as the physicians' physician.

These characteristics provide us both opportunities and create certain distinct problems. Our broad base of clincial and research activity offer expansive collaborative circumstances but sometimes is not conducive to clear identification of goals or efforts of the discipline.

Geometrical growth of the abilities, complexity and cost of radiological science instrumentation and technology has made the necessity for appropriate application of this capability acute. Effective and efficient utilization of these resources can only follow a period of appropriate assessment of the virtues and limitations of the techniques of computerized axial tomography, ultrasonography, nuclear medicine, emission tomography, nuclear magnetic resonance and other diagnostic and therapeutic modalities applied by radiological scientists. Only after the value of these opportunities in clinical medicine are determined by adequately funded protocols by appropriately trained individuals can a policy of resource allocation be developed. Implicit in this statement is request for identified funding considerations specific for this particular discipline.

While the manpower shortage in the clinical sector represented by 15,000 praticing radiologists appears to have lessened in recent years, some 30% of the 1,500 - 1,600 academic positions remain unfilled. Specific faculty augmentation grants to provide individuals with expertise in the physical and biological sciences are greatly needed.

In a consumer oriented society the consideration of biological burden imposed by radiological sciences technology has become increasingly important. The implications of energy forms such as high frequency sound waves and chronic low level radiation must be determined by funded research to address these issues.

In summary, Radiological Sciences should have more specific identification in the long range funding policies of the resources to be applied to this particular discipline. The implications of this specialty upon the cost, morbidity, and opportunities for the delivery of health care are such that public resources should be specifically applied.

A. Everette James Jr., SCM, JD, M.D.
Professor and Chairman, Department of Radiology and
  Radioloigcal Sciences
Vanderbilt University
Society Chairmen Academic Radiology Departments

RECOMMENDATIONS

(1) Identify the discipline of Radiology and Radiological Sciences as a specific area eligible for National Research Service Awards.

(2) Appoint distinquished members of the radiological sciences community, especially from the area of diagnostic imaging to a number of study sections and advisory councils within all appropriate areas of the Department of Health Education and Welfare; particularly those where radiological research and efficacy are evaluated and considered for funding (e.g. DRR, NINDS, NHLBI, NIGMS, NCI, and MIAMDD)

(3) Appointment of committees with representation from radiological sciences to study the value and cost effectiveness of radiological imaging techniques.

(4) Increased appointments of members of the discipline to the various ~~relatory~~ regulatory and advisory agencies of the Department of Health Education and Welfare that will affect the practices of radiologists.

(5) Establish an imaging laboratory in an appropriate Institute of the National Institutes of Health to develop a comprehensive intramural program for radiology.

(6) Identify an appropriate NIH institute with which extramural programs in radiological research can relate.

(7) Establish young investigator awards in diagnostic radiology available to both physicians with radiological training and basic scientists involved in diagnostic imaging and information transfer.

(8) Reestablish institutional research training grant programs in Radiology and Radiological Sciences.

CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH-PANEL TWO

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Two recurring themes have arisen in administrative and public commentary:

1. the need for an improved knowledge base for the solution of health problems;
2. the need for facilitation of technology transfer and designated funds for its support.

Concern about technology transfer was articulated in 1966 by then-President Johnson who said, "we must make sure that no life-saving discovery is locked up in the laboratory . . ."

This statement gave rise to an implicit and, I believe often spurious, separation between biomedical research advances and their implementation in the improvement of health.

Let us consider whether technology transfer is a limiting factor in the solution of health problems.

Although expensive and widespread treatment of tuberculosis in sanatoria was only minimally effective, the advent of the first specifically effective antituberculous drug, streptomycin, reduced the annual number of deaths from the disease by 51% within approximately five years (1). Although the number of Americans institutionalized in mental hospitals increased yearly by more than 4% through the first half of this century with more than 559,000 institutionalized in 1955, the advent of specific and effective drugs led to a persistent and marked decrease in the number of patients institutionalized annually and ultimately to a reduction in the number of large domiciliary institutions required (2,3). Although more than 25,000 Americans were afflicted annually with polio, the advent of specific immunization reduced the case rate from this devastating disease from 10 per 100,000 to less than 1 per 20,000,000 and prevented more than 150,000 cases between 1955 and 1961 alone (4) with an annual national savings estimated in 1972 to be as high as $2,000,000 per year (5).

In 1965, only a few hundred Americans with end-stage kidney disease were being treated by renal dialysis. Within five years after enabling legislation that defrayed costs was passed in 1972, the pool of patients treated reached 40,000. Virtually all medically eligible candidates will be utilizing this treatment program by 1982 (6). Already, in many small communities, dialysis centers exist in office buildings and other substitutes for general hospitals.

Prototypes of the revolutionary x-ray devices--CT scanners--were available only in 1972. Already, more than 900 scanners have been installed at a cost of more than $500,000,000. As pointed out in a recent report from OTA, "well-designed studies of efficacy of CT scanners were not conducted before widespread diffusion occurred" (7).

Although the first coronary artery bypass operation was not performed until 1964 and the second until 1967, and although the efficacy of this operation in prolonging life remains controversial, approximately 100,000 operations were performed within just five years after clinical introduction of the procedure. In calendar year 1977 alone, 100,000 procedures were performed at a cost of well over $1,000,000,000--approximately one-half the entire budget of the National Institutes of Health (8).

The extremely rapid dissemination of biomedical technology is readily explicable. The more than 340,000 licensed physicians in the United States in 1975 (9) had access to more than 4,000 medical journals (10) with a combined circulation of only the top five exceeding 550,000 annually. Physicians devote between 10 and 20 hours monthly to regular reading of between 6 and 11 journals (11). Continuing education courses, given by more than 1,500 institutions, have proliferated dramatically; from approximately 2,000 in 1970 to 9,000 in 1978 (12). The average adult American sees a physician 2.7 times annually in office visits (13,14). (4 times annually if emergency room and clinic visits are included)--a frequency more than two-fold greater than that in foreign cities with similar population densities. Thus, extensive exposure of medical personnel and patients to technology facilitates the extremely rapid "technology transfer" so typical of American health care. Proliferation of prescriptions for new drugs underscores this rapidity. Although less than 5,000 prescriptions were written for two agents, Inderal and Lasix, within the first month after their introduction, prescriptions for these drugs increased to 388,000 and 1.5 million respectively within one year (15).

The desire to accelerate technology transfer is fueled by political and legislative pressures to demonstrate tangible results of biomedical research expenditures. However, it is in fact difficult to identify genuine examples of failure of biomedical technology transfer.

Lister's concepts of antisepsis were implemented with a 15-year delay only because of lack of acceptance of his ideas, not lack of awareness. Syphilis in Victorian England was well recognized though the assault against it by social strictures was ineffective. Morbidity declined promptly only when the first specific anti-bacterial agent was introduced in 1908. Even without sophisticated systems such as satellite communications and computer data banks, the discovery of diphtheria antitoxin by Von Behring in the early 1900s was accepted promptly, implemented widely, and acclaimed extensively.

It is becoming increasingly clear that major advances in technology are consequences of specific advances in research which grow from an investigative environment capable of developing creative and rigorous biomedical investigators over relatively long gestation intervals. The limited funds available for clinical applications and health services research should not be expended on remedies for imaginary deficiencies in technology transfer. They should be devoted to the intensive and rigorous research required to improve the base of knowledge and validate specific apparent advances on which significant solutions of health problems depend.

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Clinical Applications and Health Services Research

Session B, No. 2

Mr. Chairman, Panel Members, Ladies and Gentlemen:

I am Edward G. High, Ph.D., Professor and Chairman, Department of Biochemistry and Nutrition, Meharry Medical College, Nashville, Tenn., a position I have held for the past eleven years. In addition, I have served and continue to serve on a number of national committees, councils, and boards concerned with health care, biomedical research, and related activities. During most of my professional life I have been involved and concerned with improving the health status of population groups through the application of basic knowledge to the improvement of health care from a local, regional, national, and international standpoint. In this connection, I was involved in the development of one of the first community nutrition demonstration projects with the objectives of improving the health status of a population group, (the target group being one of a low socioeconomic level) by applying sound nutritional and health principles to the daily activities of the participants. The results of the study have been published and the data clearly indicate that the health status of a population group can be improved through such a program.

Now, let us turn our attention to some of the major killers and cripplers of today such as allergies, arthritis, cancer, diabetes, digestive diseases, heart and vascular diseases, respiratory and infectious diseases, obesity, mental health, osteoporosis, etc. We are indeed fortunate to have various NIH Institutes involved in doing basic research in these various areas.

Although it is a moot point as to the extent that NIH should become involved in health care and societal problems, it seems that a lack of adequate follow through from the acquisition of basic scientific knowledge to its application and translation for the improvement of health care and dealing with societal problems will result in ~~a terrible~~ waste of resources, particularly with money constraints due to inflation and reduction in the real dollar.

Let us look at hypertension as a health problem. Approximately 23 million people in the United States are victims of hypertension and it is claimed that each year hypertension is a factor in 68 percent of all first heart attacks and in 75 percent of all first strokes. What this costs our national economy is staggering. Because high blood pressure is a factor in such a large percentage of heart attacks and strokes, the over-all estimated economic loss represented by arteriosclerosis as well as the hypertensive diseases is probably a more accurate measurement of the impact of this disease on the economy than that for high blood pressure alone.[1]

Direct cost of arteriosclerosis and high blood pressure totaled an estimated 4.3 billion dollars in 1967. Indirect costs due to productivity losses because of illness and disability from arteriosclerosis and hypertensive diseases in 1967 totaled an estimated 1.1 billion dollars and the estimated indirect economic costs to the nation measured in terms of the present value of lifetime earnings lost by those who died that year from arteriosclerotic and hypertensive diseases amounted to 18.5 billion dollars. Therefore, the total cost to the nation approaches a figure of 23.9 billion dollars.[2] It is obvious that hypertension is one of the major health problems of this nation.

According to data from the National Center for Health Statistics, the percentage of population ages 18-79 (non-institutionalized) with hypertension is: Black males 26.7%, black females 26.6%, white males 12.8%, and white females 15.3% with the numbers as follows: Black males 1.6 million, black females 2.1 million, white males 8.0 million and white females 11.3 million which give a total of 23 million.[3]

Besides the development of anti-hypertensive drugs, very little progress has been made in research. There is a real need for the development and evaluation of new and more effective techniques for delivering long-term care to all hypertensive patients. More research with control data is needed on the influence of nutrition and environment on hypertension which includes the development of a better understanding of the impact and influence of dietary practices and environment on the prevention and treatment of hypertension as well as the care of the hypertensive patient. A similar corallary exists with the other major health disorder. Obviously we need to continue to encourage and to develop intervention programs to reduce these staggering costs to the nation and to improve the health status of our population.

Institutions with a natural laboratory and many years of experience in the delivery of health care should be encouraged through the development by NIH of special programs dealing with the translation of knowledge by means of demonstration projects and pilot projects concerned with the improvement of health care whether it is hypertension, diabetes, obesity, arthritis, dental diseases, etc.

These programs shoul d allow for longitudinal studies with an evaluation component to give conclusive results of the impact of environmental factors including nutrition and clinical trials on various disease entities. It seems that the establishment of such programs at these institutions would not only be economically feasible and beneficial but would aid in increasing the concentration of scientific talent not only in a few areas of the country but into a broader geographic distribution, thus producing a stronger national scientific community and a stronger nation.

I thank you for the priviledge and opportunity to speak before you this morning on this very important subject.

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William F. Collins, Jr., M.D., Secretary
Society of Neurological Surgeons

Panel 2 - Clinical Applications and Health Services Research

The Society of Neurological Surgeons is composed of neurosurgical residency training program directors, professors and chairmen of medical school neurosurgical units, and other selected neurological surgeons who have or are contributing to neurosurgical education. The Society's main interests include neurosurgical education in its broadest sense. The Society wishes to present the following concepts and suggestions to the Panel on Clinical Applications and Health Services Research which it feels are relevant to this broad area.

There are no clinical areas of concern of the neurological surgeon that do not have more questions than answers and research involving any aspect of the nervous system potentially may have significance in the care of nervous system diseases and injuries. A few areas at this time, however, appear more ready for investigative emphasis with 'ready' being a term implying that associated information and techniques have matured to increase the probability of return for effort. These areas are the response of the nervous system to injury, neoplasia of the nervous system, and plasticity and regeneration of the nervous system. It is not possible in the brief time of this presentation to detail reasons for choosing these areas but rather the Society would like to point to the categories and to the overlap to other areas that any information obtained in any of these would have. The response to injury as a possible cause of secondary injury from a nervous system injury is equally applicable to the injury sustained from vascular disease or infection as it is from trauma. Neoplasia of the nervous system has unique attributes that could be utilized to study neoplasia in general with non-invasive techniques that allow accurate evaluation of growth, metabolism, vasculary and body response. The central nervous system tumors also have little tendency to metastasize. Recent advances in molecular biology, psychology, and experimental neuroanatomy indicate that a 're-look' at regeneration and plasticity of the central nervous system would be profitable. Advancement in this area would be most welcome to many citizens. Psychological techniques have advanced to the point where regeneration and plasticity cannot only be differentiated but also selectively utilized to improve function of the body.

The Society of Neurological Surgeons wishes to stress the problem of a shortage of academic neurological surgeons both at present and projected even more critically in the future. This information is based on a neurosurgical manpower survey completed within the past eighteen months. The Society believes that the lack of available funding for training of residents in basic research disciplines, and the limitation of availability of funds for neurosurgeons to do basic and fundamental research both inhibits the input into and the development of academic neurosurgeons. Lack of such people not only will impair the training of neurosurgeons in the future but will impair goal-oriented and basic research investigation of central nervous system problems such as those mentioned above. The Society of Neurological Surgeons recognizes that fellowships are available for residents but the necessity of planning a multi-year partially service oriented residency training along with the lack of ability to be certain of support for a resident when individual fellowships are applied for make them of very limited value. Residency training program support for basic research training in the past has been productive in producing academic neurological surgeons and should be re-established at least as a pilot program in a few training programs.

Finally, the Society would like to propose that the Panel recognize a continuum of fundamental and clinical research. Although the Society is most concerned with neurological surgeons, lack of support for the training of young basic neurological scientists for career development and for advanced research will be felt not only by the investigative programs that neurological surgeons are involved in but also by the country, for it is necessary to not only have a continuum of effort of research in the nervous system, but to have a stable policy with long-term planning of the input of persons with trained investigative minds as well as practitioners who can communicate with and utilize the information obtained by such research.

Gloria Rookard, R.N.
Visiting Nurse Service of Summit County, Inc.

OUTLINE - DEVELOPING MINIMUM STANDARDS OF CARE FOR HOME HEALTH AGENCIES

PROBLEM: While home health has shown great promise as a cost-effective alternative to institutional care in many instances, a careful study to establish guidelines and criteria concerning minimum standards of care for patients has not yet been conducted. It has been statistically proven that home health care is the most cost-effective method of ~~home~~ health care delivery. Data gathered from various home health agencies draw wide variations in utilization rates, and from the data alone, it is not possible to determine what minimum levels of care are most appropriate for a given patient. With the growing importance of health care cost containment and the increased emphasis on home health, it is imperative that a carefully designed and executed long-term study be conducted which, by answering questions, will help insure high levels of care for the consumer while maximizing efficiency and economy for the reimbursers. Lower cost for national health care has been of main concern for providers and users.

PROPOSED SOLUTION: What is needed is a long-term, analytic study which will carefully investigate the following points:

1. What is the appropriate minimum level of care (i.e., number of home visits) that an individual with a certain diagnosis can expect in order to maximize the desired therapeutic outcomes?
2. Who are the appropriate care-givers to deliver these services? RNs, LPNs, rehabilitation specialists, etc? Or, should a combination of disciplines be employed in order to reach the maximum level of effectiveness?

3. How does the type of home health agency (size, location, staffing, etc.) influence therapeutic outcomes and treatments rendered?

The study proposed would investigate these points and others by the use of the following techniques:

1. A group of home health agencies (possibly 6-15), somewhat diverse in size, location, staffing patterns, etc., would participate.
2. Careful documentation would be kept on patients in various diagnostic categories regarding number of visits made, disciplines making visits, etc. Each agency would treat their patients in a manner consistent with their usual methods.
3. Outcomes for each patient would be carefully evaluated. These indicators (example: number rehospitalized, number remaining at home, number experiencing further distress, etc.) would be analyzed and, based on the body of data accumulated during this logitudinal study, recommendations could be drawn concerning the most efficient and desirable minimum standards of home health care for all patients.
4. Standards would better match government regulations, clients, and services delivered.

PROBLEMS: Several difficulties would need to be overcome before such an investigation could be conducted. The most pressing would be that of sufficient funding that would allow the study to be carefully conducted over a sufficient period of time. Consistent methods of documentation and measuring outcomes would also need to be developed and utilized.

This large undertaking would require a full-time project director with sufficient qualifications to conduct the study and help interpret the data that is collected.

BENEFITS OF THE STUDY: The most obvious benefit of conducting this study would be the greater levels of efficiency and quality care to be delivered by home health by virtue of determining what is correct and proper for the patient with a given problem. Home health has already been shown to be a cost-effective method of delivering quality medical care, and the applied results of this study could go a long way toward increasing these already high standards.

Respectfully submitted,

Gloria Rookard

Mrs. Gloria Rookard, RN

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Secretary
National Black Nurses' Association

October 1, 1978

NATIONAL REYES SYNDROME FOUNDATION
P. O. Box 161 • Dexter, Michigan 48103

International Year of the Child 1979

John W. Dieckman, President
National Reye's Syndrome Foundation
PANEL 2 - Clinical Applications & Health Services Research

October 2, 1978

DOCTOR MARKS AND DISTINGUSHED PANEL MEMBERS:

I REPRESENT THE FAMILIES AND FRIENDS OF RS VICTIMS THROUGHOUT FORTY-ONE STATES AND SEVERAL CANADIAN PROVINCES WHO ARE MEMBERS OF THIS TWO YEAR OLD, MICHIGAN CHAPTERED, VOLUNTARY HEALTH ORGANIZATION FORMED TO COMBAT A HEALTH PROBLEM AFFECTING NEWBORNS TO YOUNG PEOPLE IN THEIR TWENTIES AND SOME ADULTS IN THEIR THIRTIES.

REYE'S SYNDROME IS THOUGHT TO BE A DISEASE WHICH DID NOT PREVIOUSLY EXIST IN PRESENT PROPORTIONS AND IS INCREASING IN BOTH INCIDENCE AND SEVERITY. NO QUANTITY OF STATISTICS EXIST THAT CAN ADEQUATELY ILLUMINATE FOR US THE EXTENT OF THE PROBLEM. IT IS NOT NEW FOR ITS PATHOLOGY HAS BEEN NOTED IN MEDICAL ARTICLES SINCE 1925. AS A SYNDROME IT IS ALL THE MORE COMPLICATED AND DEVASTATING. IT MAY REPRESENT MORE THAN ONE DISEASE PROCESS WITH SIMILAR OR DIFFERENT ETIOLOGIES, BUT WITH A SIMILAR PRESENTATION. IT MAY DIFFER IN SEVERITY BY LOCALE.

THE IMPACT OF REYE'S SYNDROME ON SOCIETY IS COMPARABLE TO THAT OF POLIOMYELITIS IN THE 1920's, BEFORE IT HAD NATIONAL CONCERN.

FUNDEMENTAL RESEARCH IS ALWAYS PROVIDING ANOTHER "GRAIN" OF VITAL BASIC KNOWLEDGE. SPECIFIC RESEARCH PROJECTS ARE BEING FUNDED HOWEVER, THE PROJECTS AND FUNDING HAVE BEEN MINUTE IN COMPARISON TO THAT OF OTHER KNOWN AND BETTER PUBLICIZED DISEASE ENTITIES.

THERE IS NO KNOWN MEANS OF PREVENTION SINCE CAUSE HAS YET TO BE DETERMINED! THERE IS NO EFFECTIVE MEANS FOR EARLY DIAGNOSIS! WORK IS BEING SUPPORTED IN THIS AREA BY MEMBERS OF THE ROCKY MOUNTAIN REGION

NATIONAL OFFICERS
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MEDICAL ADVISORS
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REGIONS
NEW ENGLAND
WILLIAM CALDWELL, President
ROCKY MOUNTAIN
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SPECIAL ADVISORS
C. GARRITT BUNTING, Financial
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HONORARY TRUSTEES
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JACK TOEPP, State Senator, Michigan
CONNIE BINSFIELD, State Representative, Michigan
THOMAS NORTON, State Representative, Massachusetts

OF THE FOUNDATION. EFFECTIVE TREATMENT METHODS AND TECHNIQUES ARE NOT AVAILABLE GIVEN A AVERAGE MORTALITY RATE OF 40% NATIONWIDE, RANGING FROM 25% to 80%. METHODS USED ARE NOT UNIVERSALLY ACCEPTED NOR ARE THOSE USED APPLICABLE FROM ONE PATIENT TO ANOTHER. SEVERAL TREATMENTS HAVE BEEN TRIED BUT NONE HAS ACHIEVED UNIVERSAL SUCCESS OR ACCEPTANCE.

TO THE MEDICAL SCIENTIST, INDEED TO ALL OF US, CURE AND PREVENTION ARE THE NUMBER ONE GOALS. HOWEVER, TO THE PATIENT AND PARENTS, CAUGHT UP IN THE IMMEDIATE, EMOTIONAL IMPACT OF DEALING WITH A DISEASE ENTITY THEY PROBABLY HAVE NEVER HEARD OF, THE FACT THAT THERE IS NO TREATMENT PROTOCOL THAT CAN GIVE THEM RELIEF BECOMES PARAMOUNT TO THE MOMENT OF HEALTH NEED.

STRATEGIES MUST BE DEVELOPED AND ADOPTED FOR FUNDING HEALTH RESEARCH THAT INCLUDE PROVISION FOR SPECIFIC PROGRAM EXPANSIONS IN SUPPORT OF CLINICAL APPLICATIONS, CLINICAL TRIALS AND HEALTH SERVICES RESEARCH ACTIVITIES AS DIRECT ADD-ONS TO PROGRAM NEEDS. THE PUBLIC, ACADEMIC AND PRIVATE SECTORS SHOULD BE PART OF THE PROCESS. IMPROVEMENT OF COMMUNICATIONS AND INFORMATION EXCHANGE BETWEEN MAJOR TREATMENT, RESEARCH AND ACADEMIC CENTERS AND THE INSTITUTES SHOULD OCCUR SO THAT ADVANCES ARE ASSIMILATED INTO THE SYSTEM AND SOCIETY MUCH SOONER AND MORE EFFECTIVELY. THE HUMAN EXPERIENCES OF HEALTH NEEDS SHOULD PLAY A MORE DOMINANT ROLE IN ADDRESSING HEALTH CARE REQUIREMENTS. A FEW DISEASE ENTITIES SHOULD NOT RECEIVE THE MAJORITY OF THE HEALTH RESEARCH DOLLAR CONTINUALLY, AT THE EXPENSE OF OTHER PROBLEMS BEING COMPLETELY IGNORED OR PAID ONLY LIP SERVICE.

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International Year
of the Child 1979

NATIONAL REYES SYNDROME FOUNDATION
P. O. Box 161 • Dexter, Michigan 48103

SPECIFICALLY, REGARDING REYE'S SYNDROME, THE FOUNDATION BELIEVES THAT NIH SHOULD INITIATE TALKS LEADING TO ESTABLISHING AND FUNDING A NATIONAL, COLLABORATIVE, MULTI-CENTER STUDY DIRECTED TOWARDS DETERMINING STANDARD CLINICAL, PATHOLOGICAL AND BIOCHEMICAL DIAGNOSTIC CRITERIA FOR THE VARIOUS PHASES OF RS AND ANTI-CEREBRAL EDEMA THERAPY. SUCH A STUDY INVOLVING LARGER PATIENT POPULATION WILL ENABLE INVESTIGATORS TO ACQUIRE SIGNIFICANT CONCLUSIONS REGARDING ETIOLOGY, EPIDEMIOLOGY, VIROLOGY, METABOLISM AND TREATMENT OF RS.

NOW IS THE TIME TO BE INNOVATIVE AND AGGRESSIVE FOR NEW DISEASES ARE CHALLENGING OLD ONES, AS YET UNSOLVED, WHILE FRESH, YOUNG INVESTIGATORS CHAFF AT THE BIT, UNUSED BECAUSE OF ESTABLISHED PRACTICE AND BUREAUCRACY.

I WISH TO EXPRESS OUR VERY WARM APPRECIATION TO SECRETARY CALIFANO, DIRECTOR FREDERICKSON FOR THE INVITATION TO ATTEND THIS CONFERENCE. WE HOPE THAT OUR PRESENTATION, IN SOME SMALL WAY, WILL BE OF SOME HELP IN THIS MOMENTUOUS UNDERTAKING.

THANK YOU.

John W. Dieckman

John W. Dieckman

[redacted]

NATIONAL OFFICERS
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THOMAS NORTON, State Representative, Massachusetts

Public Testimony

Submitted by:
Mary Lynn Porter, Director
Auburn Day Care Centers
Auburn, Alabama

Submitted to:
Panel 2 - Clinical Applications and Health Services Research
National Conference on Health Research Principles
National Institutes of Health
Bethesda, Maryland

October 3, 1978

I come before this panel as a user of research, rather than a doer of research. I give direction to federally funded child care centers in Auburn, Alabama. My staff and I are doing the best we can with what we know. Children are being adequately cared for (loved, fed, exercised, taught and disciplined) under my supervision.

A year ago, I was appointed to the National Advisory Child Health and Human Development Council. Suddenly I was in the middle of discussions of research priorities and projects, and decisions concerning research funding. With this involvement came a new awareness of a reality with which I had not been faced so vividly before. Some of the most complex problems we deal with, and some of the most perplexing questions we ask each other about our children and their families at the child care center, are being dealt with in the main stream of the research arena. Somebody is discovering some possible answers and solutions, is seeing some trends develop and reaching at least some tenative conclusions, and we don't know what they are in the Auburn Alabama's of the country.

My experience is narrow, but my concern is broad. Concern that I and others like me, the college trained grass roots user of research findings, receive such findings in usable, meaningful form, in order to up-grade the services we offer - thereby better meeting the human need we see.

Research studies and findings are available to us through research journals and research forums at professional conferences, but with the abundance of research in any given area we need help in the synthesis effort. Also, we do not have the background to evaluate studies, interpret findings and translate applicable findings into appropriate implementation. We need help with this.

Since the purpose of research is not to perpetuate research, but to improve lives, it seems of top priority that we establish a process whereby I can know what research shows about what's best for children and families; being particularly aware that such a synthesis and disimination process for the behavioral disciplines has its own unique problems.

We are all aware of how crucial early years are in a child's development. It is in these years that problems prevented or remediated can make the difference in the whole life. Recent articles in the Wall Street Journal, Washington Post and Star deal with the issue of child care for pre-school children. Although reactions are mixed toward child care and its effect on children, one fact is sure... five million children are now cared for outside the home and the percent will continue to increase.

At the child care center we have access to these children for a large portion of their day. We must be able to justify to parents and to society, as well as to the children and ourselves, how we spend this time; that it utilizes the best that is known from the research arena. The staff is involved with the child as whole person, the physical/motor, cognitive/language and affective domains. What we do prepares a child for the person she/he will become. It would be inane, and insensitive, for us to believe otherwise. We are in far too important and responsible a position to be allowed to muddle along hoping that what we are doing is not missing the mark. The American family has far too many needs for us to make such inefficient use of our opportunity.

It is from health research that our best assistance can come. From this forum can come an inter-disciplinary, developmental approach to the study of the child and family. Being keenly aware that one facet of a child's being so dramatically effects all other development, you address the child. It is only in this approach that the hard questions can eventually be answered.

As we develop a process whereby we work together... the researcher and the practitioner, we will be able to make a significant difference. During 1979, the International Year of the Child, as planning is done, when priorities are set, and when monies are allotted, we must bring in a decade where it is obvious that we see children as foremost. It will be, at the least, short-sighted to act otherwise.

Dr. David Wayne Smith
Assistant Vice President for Health Sciences
University of Arizona, Tucson, Arizona

Member, National Arthritis Advisory Board
Chairman, Community and Rehabilitation Work Group

In this brief presentation I wish to speak in support of Secretary Califano's call for government-supported research having a strong orientation toward improving the quality of our nation's health and the effectiveness of this country's health services. The Secretary has made a very powerful argument in favor of such research support when he questions whether the billions of dollars in federal support for health care have had a significant impact on the health of the American people. While the Secretary makes no reference in his paper to a particular time frame, this problem has accompanied the entire history of federal intervention into health care.

A critical analysis of the large scale federal participation in health care may actually show the abuses and excesses to far outweigh the achievements. No such effort should ever have been undertaken until the traditional systems for delivering health care had been subjected to rigorous evaluation.

I am also concerned about the integrity of the pending broader federal initiative into health care since the evidence seems to suggest this may further erode the consumer/taxpayer return on the federal health care dollar.

One cannot help but wonder how those responsible for these federal health care initiatives could have failed to parallel such efforts with well-conceived applied research strategies designed to examine alternatives to traditional health care delivery, including but certainly not limited to, evaluation of the role in primary care of such well qualified professionals as nurses, nurse practitioners, physicians' assistants, and health educators. In arthritis care alone the federal government has had the opportunity to develop carefully controlled studies in community health care where the value of the role of different health professionals could have been assessed over an extended period of time including studies of cost effectiveness and improved functioning.

In the integrity of the original mission of the National Institutes of Health with its initiative and funding of basic and clinical research, and the preparation of investigators to enter their respective fields. DHEW had the model for studying the applied problems of health care delivery. The same high standards, including peer review, should have been advocated and supported by federal research

GRANTS TO QUALIFIED RESEARCHERS IN HEALTH CARE DELIVERY THROUGHOUT THE PAST 25 YEARS.

IT IS QUITE PROBABLE THE FINANCIAL BURDEN OF HEALTH CARE DELIVERY RESEARCH COULD HAVE BEEN PAID FROM THE COST TO THE FEDERAL GOVERNMENT OF THE ABUSES WHICH HAVE BEEN WELL DOCUMENTED THAT HAVE ACCOMPANIED THE FEDERAL INTERVENTION PROGRAM. THIS FACT ALONE SHOULD BE SUFFICIENT EVIDENCE TO CAUSE DHEW TO MOUNT A LARGE SCALE PROGRAM OF RESEARCH IN THE AREAS BEFORE OR AT LEAST PARALLELING THE NEXT EXPANSION OF FEDERAL HEALTH CARE INTERVENTION.

STUDIES IN COMMUNITY HEALTH CARE DELIVERY FOR ARTHRITIS PATIENTS WERE RECOMMENDED BY THE NATIONAL COMMISSION ON ARTHRITIS AND RELATED MUSCULOSKELETAL DISEASES IN A REPORT TO THE CONGRESS DATED 1975, AND FURTHER SUPPORTED IN THE 1977 ANNUAL REPORT OF THE NATIONAL ARTHRITIS ADVISORY BOARD (SEE ATTACHED DOCUMENTS).

BREAKING WITH THE TRADITIONS IN HEALTH CARE DELIVERY THAT CURRENTLY DOMINATE THE COMMUNITIES OF THIS NATION AND WHICH MAY ALSO HAVE CONTRIBUTED TO OUR CURRENT CRISIS WILL NOT BE ACHIEVED BY RESEARCH ALONE. JUST AS THE RESEARCH STRATEGIES MUST BE WELL PLANNED SO MUST THE INTERPRETATION OF FINDINGS TO THE CONGRESS AND TO THE ADMINISTRATION BE CAREFULLY CONCEIVED.

In order to increase the supply of qualified personnel to conduct the type of research called for in this paper, the federal government should increase financial support of public health, nursing, and allied health. It is particularly important to increase such support to schools located in health sciences centers, which is commensurate with Secretary Califano's call for medical schools to work with such schools as full partners.

Finally, I support the need to develop a national, federally funded clearing house where descriptions of completed and ongoing applied research by scientists is systematically compiled and disseminated.

IDA MARIE MARTINSON, R.N., PH.D.

Professor of Nursing
University of Minnesota
School of Nursing

Testifying on behalf of

AMERICAN NURSES' ASSOCIATION

Commission on Nursing Research

Panel II - Clinical Applications and Health Services Research

Today, doctorally-prepared nurses are actively involved in research; not only in fundamental research, but also in research in clinical applications. For example, Dr. Kathryn Barnard at the School of Nursing, University of Washington, Seattle, has a research grant to study the effects of various environments in early development in preterm infants. Specifically, she is looking at the effects of various stimulations on weight gain. Dr. Gene Anderson-Shanklin, College of Nursing, University of Florida, is studying development of sucking and the ability to feed in new born infants. Both of these studies are examples of nursing research which aim to improve care of high risk groups.

Other efforts of nurse researchers to expand the scientific base of health care include animal studies. A preliminary study using rats indicates that a 30-40° C. abdominal application would not affect intra-abdominal temperature readings. That animal study, which is currently underway, evolved from a clinical incident where a child with internal bleeding requested a hot water bottle for comfort. The child was refused the hot water bottle on the basis that it would increase internal bleeding. A review of the literature revealed the effects of surface heat to the abdominal area and its internal effects are not known. Although further study needs to be done, there is some indication that the child could have received the hot water bottle for comfort without increasing internal bleeding.

My own research, funded by National Cancer Institute, initiated July, 1976, investigates the concept of home care for the dying child. The study was designed to systematically identify the needs of the child and the parents during the end-stage of cancer, to identify factors in the decision of parents to care for the child at home, and to identify what professional services are necessary. The findings to date indicate most children express a desire, either verbally or by action, to be at home and most parents accept the home care concept and demonstrate they are capable of caring for their child in the home setting under the direction and with support of a professional nurse. Analysis of costs in this study indicates that care of the child at home has an estimated average of $1200 compared to analysis of costs of a similar group of children who died in the hospital prior to the study whose average final hospitalization cost was $13,000. Other questions remain, for example, the long-term effects on family and siblings, the implications for the health care delivery system, and coverage by third-party payors. Continued research is needed in these and other areas as well as study of the cost effectiveness of consumers being more active participants in their own health care.

Thus, there is beginning evidence that nursing research can have a definite impact on health care, including development of alternate methods of health care delivery which are cost effective. From the models that are developed by nurse researchers, the consumer, the public and professionals will choose the alternative health care model that best suits their situation.

Esther Winterfeldt Phd, R.D.
American Dietetic Association
Panel on Clinical Applications
and Health Services Research

Today I am representing the American Dietetic Association, a professional association of 36,000 members with the goal of promoting good nutrition for all persons. Dietitians translate the science of nutrition into the selection of foods people eat. We believe that good nutrition is central to optimum health and to the prevention of disease throughout life. Further, the application of nutritional science to health care is being increasingly recognized aa a priority area of need. The avowed need for a National Nutrition Policy and the recent issuance of the Dietary Goals for the United States both speak to this. The spotlight is on nutrition as a way of life and the need to focus on the research needs to allow this to become a reality is urgent.

Dietitian and nutritionists are, in varying ways and extent, involved in the planning and execution of comprehensive health care programs, in nutrition education programs for the public and in nutrition training for other groups involved in health care and education. Responsibilities and functions in health care settings include primary prevention through assessment of nutritional status and food practices, diet counseling, consultation in group care facilities, training and education; in secondary prevention in acute and intensive care through participation in health team planning, planning and supervision of appropriate food services; and in restorative and extended care through assistance in adjusting the home environment to permit optimal food intake and in contacts with other needed service agencies.

Steps in all health care programs necessarily include assessment, diagnosis, treatment, education with follow up, and long term monitoring.

We submit that nutrition research will help identify the ways that nutrition is a basic ingredient in each stage.

There are, at present, deterrents in several areas to provision of optimum nutritional care in the clinical setting. These include:

1. Universal recognition of the fact that nutritional care is basic to health care is absent.
2. Adequate funding for nutrition services in preventive care is not available.
3. Recognition of the need for ongoing support for research in the basic science of human nutrition and in systems of nutritional care delivery is needed.
4. Inclusion of nutrition in the curricula for madical, dental, and other professional health care personnel and its evaluation is needed.
5. The role of the dietitian as a physician extender in planning and implementing continuing care in settings outside acute care facilities has not been adequately recognized.

The clinical application of nutrition services related directly to the principle stated in the plans for this conference, i.e., such services are aimed toward improvement of the quality of health care and toward prevention of diseases and therefore reduction in the burden of health care costs. To this end, an extended knowledge base through the support of applied, problem-oriented research is vital. Malnutrition in varying degrees may actually be the nation's primary health problem. We are informed that human nutrition research receives about 3 percent of the 3 billion now being spent annually on all agriculture and health research. Further, the research is fragmented among governmental agencies and groups and needs focus and direction.

A 1978 report from the U.S.General Accounting Office to the Congress on Human Nutrition Research needs indicates areas in which further research is needed. These include:

1. Definition of human nutrition requirements for growth and well being during pregnancy, infancy, lactation, childhodd, and adolescence, and for women, the elderly, those with disease and stress, and those taking drugs and vitamins.

2. Ongoing monitoring of the nutritional status of the population and identification of those at risk.

3. The relationships between nutrition in disease conditions such as diabetes, cardiovascular disease, obesity, osteoporosis,, cancer, gastrointestinal diseases and others known to be related to nutritional factors.

4. Evaluation of the health consequences of the modern diet.

5. The study, development and coordination of standards for nutritional care.

6. Narrowing of the gap between nutritional knowledge, food technology and food production.

Human nutrition research has entered a new era, marked by growing evidence implicating diet as a major cause of disease and by increasing public concern about nutrition. To determine the diet's potential for helping reduce disease and related health care costs, nutrition research faces complex challenges needing long-term and interdisciplinary investigation.

Thank you.

national
RIGHT TO LIFE
committee, inc.
NATIONAL OFFICE — Suite 341, National Press Bldg. — 529 14th Street, N.W. — Washington, D. C. 20045 — (202) 638-4396

October 14, 1978

Mr. Kurt Habel
Chief, Program Planning Branch
D. P. A., O. P. P. E.
Office of the Director
National Institute of Health
Building 1, Room 205
Bethesda, Maryland 20014

Regarding: National Conference on Health Research Principles
October 3 - 4, 1978; National Institute of Health
Bethesda, Maryland

Primum non nocere - First, do no harm - the foremost medical admonition from antiquity is daily violated by our medical and nursing caretakers with Federal leadership in our society which is rapidly becoming an abortion culture. In order to do this we in society in general and in our medical community in particular must think of the person from conception on as a non-person or pre-individual rather than a real and alive human who would proceed through all the other developmental stages if not attacked and gotten rid of by ironically the very people in the society trained to be responsible for the sustaining of the life of each person. Such words as embryo and fetus and especially the more recent experimental biologist phrase used "human material" are much less disquieting to use rather than the simpler words such as baby or person and, because acknowledging reality for which the words stand as symbols, would certainly make unconscionable our our continued stopping the lives OF THE SILENT MEMBERS OF OUR HUMAN COMMUNITY.

II

From conception on each human individual needs minimally to be allowed to exist. Such basic right is not abridged by us older individuals - even by the millions - proclaiming vociferously that the younger person does not yet exist in any truly human way; the the continuing existence of any human should not be dependent on mere accidental circumstance of how they are defined expediently by the individual in whose body they happen to exist or the society which is defining them legally or medically at the present time. We cannot pretend logically that the baby has not said hello to the human community before we acknowledge our saying goodbye through abortion, no matter how we try "humanely" to rationalize our behavior.

In order to hopefully remedy the complex human needs of all reflected in our abortion dilemma nationally the following fulfillable prescription is respectfully submitted:

> Under the central sponsorship, initially of our Federal Government, Centers for Human Caretaking could be developed. These centers would involve all professionals from our communities orchestrated effectively with voluntary resources as centers of advocacy for each and every human being from conception throughout natural life time - no matter what the brevity or human differences might be. Each person

III

should be under the protective mantle of our national community without the threat of being terminated because of mere human circumstance - for example being preborn, retarded, coming at an inconvenient time, economic depression or any other special needs. Working theoreticians and practitioners from each of the health, educational, welfare, bioethical, and socio-economic communities could be centered initially at the National Institutes of Health in a pilot center to seed throughout the nation on state and local levels other centers, especially in medical, nursing and social work schools.

It is appreciated that in our pluralistic society with different ways of caring that the matter of aborting or not the preborn person is truly mutually exclusive and cannot logically coexist for we either take care or get rid of the preborn person.

In this Federal city as our nation's capital last year 2½ times the number of people allowed to be born were reported to be aborted.

Each of us as individuals and collectively in groups called families, movements, professions, governments, or courts has to contend with the multiplicity of feelings about life - our own and our sense of others. Such mixture of feelings may be called ambivalence, most of which is outside our reflective awareness

IV

but such powerfully directs our behavior and feelings, ~~but~~ Yet some very importantly is within our conscious awareness. Our ambivalence about life is reflected IN where we stand on such issues as abortion, suicide, capital punishment, war and euthanasia. Powerful pressures within each of us and between all of us can influence our choices and actions in these critical areas. Because of the enormity and complexity of what is involved it is a minimal expectation that our same government which has so definitely taken stands on HEW and Supreme Court levels regarding these issues in general and abortion in particular should at least representatively invest the modest resources embodied in the concept of centers for human caring. Ranging from the special needs of the preborn person and mother and all others attempting to be supportive of the lives involved to the other end of the human spectrum as represented in the terminal stage of life by the current hospice efforts nationally, our government is obliged to invest its effort in caring for our people in such a program as the centers for human caring. We are herein asking our government to allow us to be more effective caregivers rather than unrealistically burden our government with requests that it be the caretaker.

National Right to Life, Inc. would gladly participate in any and all efforts to establish centers for caring.

Submitted by:

Edward J. Sheridan, M.D.
Clinical Associate Professor
Georgetown University School of Medicine

Professional Advisor; National Doctors for Life

Professional Advisor; National Right to Life Committee, Inc.

10/2/78

STATEMENT BY
SAM SHAPIRO*
FOR PANEL ON CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

In appearing before this panel, I wish to express support for the various statements in Attachments 2 and 3. They address critical issues that need attention if health services research is to increase its effectiveness in identifying problems in the health field, their correlates and possible solutions. My comments that follow are primarily concerned with extensions of a number of the statements in the document.

The present draft of principles before you projects a distribution of responsibilities for substantive and methodological research in health services among many agencies. This is crystallized in the final statement, page 11 of Attachment 2, on the need to maintain the present pluralistic approach in these areas. There is great value in pluralism and it is neither possible nor desirable to concentrate all research concerned with health services in a few selected DHEW agencies. However, it would be important for the principles to reflect the fact that health services research is a specialized field of activity that requires professionals; resources and an organizational structure dedicated to the development and dissemination of knowledge in this area. Health services research has been practiced for many years but it is only during the past 10-15 years that it has emerged as an identifiable field, and this has been in response to the recognized need for sustained attention to the complex and durable issues faced by policy makers, planners and administrators concerned with health services.

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* Director, Health Services Research and Development Center, Johns Hopkins Medical Institutions and Professor, Health Services Administration, Johns Hopkins School of Hygiene and Public Health

The value of an organizational focus for advancing the scientific base of health services research and its application is, of course, attested to by the provisions of the Health Services Research, Health Statistics and Medical Libraries Act of 1974 (PL 93-353). I would urge the adoption of a principle that is consistent with this view.

The drafted principles call for the strengthening of planning and coordination among DHEW agencies concerned with clinical applications and health services research. The importance of such a step, particularly in light of the reference to "new funding arrangements", is considerable and it is urgent that it move ahead. Practitioners of health services research are well aware of the interdependence between the solution of problems related to coordination, availability, accessibility, organization, appropriate utilization, costs and quality of care when our concerns are directed at the systems of care and the application of these solutions to issues defined in categorical terms of disease or specific age groups. Outside of DHEW, many health services research centers have been making contributions in both areas to the benefit of program and planning agencies. Examples are found in the response to the NHLBI initiatives in hypertension control, in the efforts to develop community-based cancer control programs under NCI support, and in the increased attention being given to research related to children and the aged. It would be highly desirable for the final statement of principles to expand on the necessity for inter-agency coordination and resource allocation by identifying the principal agencies involved and to take the position that a Council be formed for this purpose with representation from within and outside DHEW.

Recognition is given in the drafted principles to the necessity of "multi-year, high cost investigations and clinical trials" and to the desirability of allocating funds as direct add-ons to specific agency programs. This should be paralleled by a principle on the need for long term, high level support for methodological development and research on health services issues that cut across agency programs, with funding going directly to the agencies that have continuing, specific responsibilities for health services research. Measurement problems in the health services field are difficult and will not be resolved satisfactorily without extensive investment over long periods. The relevance of these problems for clinical applications is clear when we note that a major effort is still required in the development of valid and reliable measures of health status for inclusion in studies of effectiveness of health care and prevention. Also, it is important to reflect in the principles the fact that many of the questions in the health field affecting clinical program applications require broad, long term investigations of the influence on health care behavior and health status of facilities, management, staffing, distribution, organization, and financing under alternative health care systems. As mentioned previously, there is an interdependence between knowledge developed on system-wide issues and information requirements for categorical programs. The provision for interagency coordination linked to new funding arrangements that make possible collaboration among the agencies, also previously discussed, can be exceedingly important. However, unless the primary agencies responsible for health services research are adequately funded directly, the broader aspects of health services problems will not be appropriately addressed.

Although another panel is concerned with questions related to research capability, including recruitment and training for health services research, I believe the issue is relevant for this panel because its consideration clarifies the significance of an organizational focus for health services research. Experience indicates that many of the problems in the health field need to be addressed by multi-disciplinary groups. Actually, there are few investigative areas as dependent on this approach as health services research. The disciplines that are requested include biostatistics, epidemiology, medicine, medical sociology, health economics, operations research and computer sciences; in many cases the disciplines of law, political science and management have prominent roles. The point is that no single discipline dominates the field and that the practitioners of health services research are drawn from many disciplines. Rentention of personnel from these disciplines in the field of health services research does not require relinquishing identification with the disciplines in which they were trained and gained experience. The more important considerations are the development of a commitment to the field because of the issues involved, a command of a subset of the tools needed to engage in research, and the existence of suitable environments for research and adequate support. These conditions can best be satisfied by strengthening the position of organizational structures within and outside Government that are dedicated to the tasks of health services research.

My final comment concerns the functions of health services research, many of which are well identified by the principles in the document prepared for this national conference. An explicit statement that recognizes the role of health services research in identifying need for change in local programs and evaluating alternatives for dealing with them would be valuable. This function carries with it the requirement of achieving close proximity to operating programs, considerable knowledge as to how they function, and effective dissemination of findings to increase the likelihood that they will enter into the decision-making process in local and regional planning bodies and at the administrative level in health care systems. This should not be interpreted as diminishing the role of health services research in developing intelligence that is relevant for broader policy formulation. The emphasis on local and regional applications is designed to reflect the fact that change often requires a particularization that is close to the firing line.

NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

Testimony to Panel 2 (Clinical Application and Health Service Research)

by

Paul Sherlock, M.D.
Chairman, Department of Medicine, Memorial Sloan-Kettering Cancer Center
Professor of Medicine, Cornell University Medical College
President, American Society for Gastrointestinal Endoscopy

In the past 2 decades enormous technologic advances in diagnosis have been made and we assume they will continue at or near their present pace. Such a recognition necessitates the establishment of a policy for evaluating and incorporating new tests into the overall diagnostic framework. A framework has never been developed for the incorporation of new tests within the existing tests. Often the evaluation of a new test is isolated without consideration of how it would fit into the total diagnostic schema.

The precise process by which a physician makes a diagnosis is not fully known. It is an amalgamation of the patient's complaints, history, physical examination, selection of diagnostic tests and the physician's judgement. The physician forms his estimate of the value of a given test in a particular situation from many sources, some of which may be based on word of mouth discussions. Tests are sometimes ordered due to popularity, habit or external pressures. Old tests may remain in use without regard to their diagnostic yield because of lack of reliable, easily-available facts about the test.

The ordering of diagnostic tests may be affected by the fear of malpractice litigation and this so-called "defensive medicine" encourages the indiscriminate use of tests. Cost is not often a consideration in test selection. Few physicians are informed of the cost of various tests and third-party payment relieves the patient (and the physician) of direct concern with the cost of a specific test.

The physician's responsibility in cost-containment is to make use of diagnostic test resources as efficiently as possible. The most effective approach to cost reduction of patient care in the area of test use would be to provide the physician with a cost-saving diagnostic strategy plus up-to-date information on a test's efficacy and suitability. Methods are needed for communicating new approaches to the physician encouraging them to incorporate test information into their practice. There is great waste in lost, unrecorded or poorly-recorded test data. The transferring of laboratory data among physicians is inefficient, requiring repetition of tests. Evaluation of the effectiveness of screening techniques for the early detection of treatable diseases such as cancer of the colon is needed, because inadequate screening techniques result in overuse of tests. An unknown, but potentially large body of superfluous testing, stems from the lack of tests the physician can use to identify common functional disorders such as the irritable colon syndrome for which no reliable objective tests are available. Consequently, those who suffer from these disorders undergo large numbers of unnecessary tests in the process of excluding all other possible organic illnesses.

We have no consensus as to the proper sequencing of certain tests and techniques such as radiologic, nuclear, ultrasonic and endoscopic studies. Research directed at aiding practicing physicians in making proper sequences of diagnostic tests for specific conditions in order to spare the patient unnecessary tests and to achieve cost-containment would be an enormous step forward. The development of algorithms (rule or patterns for solving problems particularly when common denominators can be established) would allow the physician to investigate the cause of a specific symptom or finding in the most efficient, economical and least invasive manner. Decision analysis, probability theory and Delphi opinion resolution could be employed to devise such algorithms for appropriate use of tests. With algorithms a minimum of time, money and physical or emotional distress for the patient could be expended in arriving at a diagnosis.

New techniques have been recently developed in endoscopy, radiology, scanning and ultrasound that greatly improve diagnostic accuracy but experience with such techniques has not been scientifically evaluated. Each must be tested for effectiveness, risk and cost, and determinations must be made as to which techniques are best suited to specific problems. Assessment of the usefulness and efficiency of diagnostic procedures is essential to their refinement and critical to their cost-effectiveness. It is therefore recommended that studies of diverse diagnostic approaches (for example, endoscopy vs x-ray) should be funded by agencies that deal with health care research. Drawing upon expertise in such fields as medical economics, sociology, biostatistics and computer technology as well as medicine would be helpful in evaluating these controlled clinical trials.

With the development of sophisticated instrumentation, there is substantial evidence to suggest the design of clinical instrumentation has greatly expanded the potentials of research. For example, instrumentation has made it possible to study the circulation of injected dyes through very small passages and to study secretions collected directly from ducts in the pancreas. Additional research on instrumentation oriented to clinical research needs would greatly enhance our research capabilities, and for this purpose more funding is needed.

In conclusion, the very rapid technologic proliferation that has been occurring in the past 1-2 decades runs the danger of the technology outstripping the clinical usefulness while multiplying the costs of medical care. Research to delineate strategies now will save difficulties later.

My name is Barbara J. Syska. I am employed by the National Right to Life Committee Inc. I am going to speak today about research in the area of my interest, however, concerning only the beginning of life; and I will speak of research in a broad sense, that is, clinical research with strict protocol as well as gathering demographic data and other statistics.

The aim of research is finding the truth. To defeat that aim, to hide the truth, one can use one of three dishonest ways:

I. One can draw the wrong conclusion to his finding by altering the numerical values obtained or by generalization beyond the scope of the investigated area.

II. One can supress the results obtained, if they did not follow one's wishes.

III. But the easiest way is not to do the research in the area where the results expected would not be what one wishes to obtain.

Unfortunately, in the area of my interest, there is an abundance of Government funded research, or research done by Government institutions which use all of the above three ways of hiding the truth.

In the first area a perfect example is the study done by National Institute of Child Health and Human Development on the safety of amniocentesis. (1) Amniocentesis is used now primarily to search for handicapped children in order to destroy those inconvenient for the community. In order to achieve this goal, women must accept amniocentesis, therefore a study was needed to show that amniocentesis is safe. So a study was done. Controls were badly matched according to age, so although seemingly making the conclusions even stronger, the loss of children by the control group was made easier, and the sample was too small, mainly of high socioeconomic group. However, authors claimed that their study can be generalized to amniocentesis as a whole. I have seen to date several studies which start by saying that amniocentesis is safe, and quoting as the only reference the NICHHD inconclusive study.

Another example was a calculation done by CDC (2) of what would happen if Government funding of abortion would stop. The enormous increase of maternal deaths if women would choose childbirth instead of abortion reached even the Congressional Record. The authors never admitted that they made an error in calculation. Even if one accepts their strained assumptions that error ^ results in increase of the number of maternal deaths by 33%.
calc...

The example of the second way is the prospective study of consequences of abortion for the future reproductive health of women, done in New York and Government funded (3). The gathering of the data was already finished by June 1977. The preliminary results showed that consequences were much more serious even than what could be expected from the studies done abroad, which are usually dismissed as not applicable to American women. One would expect that the preliminary data would be on the front pages of every newspaper, that all the medical journals would write about it. But... so far nothing has happened.

The third way is rich in examples. The number of abortions grows enormously from year to year especially among the young. So does the suicide rate, especially among the young. Where is the study of the possible causative correlation between these two phenomena? Not one exists so far.

What about the sterilizing effect of abortion: who studies this problem?

What are the short term consequences of abortion? National Center for Health Statistics intends to gather data on the subject. The form to report abortions and its consequences was recommended by Technical Consultant Panel and is being recommended by the National Center for Health Statistics to the states. The form contains the date of abortion, but does not list the date when the report was filed. Was it filed immediately, thus no complications which appeared a few hours later would be reported, or was it filed very late, and part of the history was forgotten. There will be no date on the report. That way the effort will be extended and nobody will know the true incidence of consequences of abortion. Is the intent of the form to find or to hide these consequences.

How is the problem of fetal death studied lately? In most states fetal deaths are definded, in accordance with international guidelines, as death occuring 20 weeks after conception. However, I was informed by the Director of the National Center for Health Statistics that death of a child by abortion is not counted as fetal death even when it occurs after 20 weeks gestation. According to the Supreme Court, the fetus is not a person. According to the National Center for Health Statistics the fetus is not even a fetus unless wanted.

In conclusion I want to appeal to researchers, peer review committees and anyone in any way connected with funding or conduction of research: Please, return to research its old fashioned aim - finding the truth.

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GOOD DAY MR. CHAIRMAN; MEMBERS OF THE PANEL; OTHER DISTINGUISHED GUESTS AND VISITORS:

MY NAME IS THOMAS J. BYRNE OF MASSACHUSETTS, REPRESENTING THE MASSACHUSETTS CHILDRENS' CANCER BLOOD PROGRAM AND THE CITIZENS COMMITTEE FOR THE CONQUEST OF CANCER, DENVER COLORADO.

I AM THE FATHER OF A NINE-YEAR OLD SON WHO HAS HAD CANCER. HE IS ONE OF THE FEW WHO HAS SURVIVED, THANKS LARGELY IN PART TO THE ADVANCES IN CANCER TREATMENT. MY PERSONAL INVOLVEMENT PROMOTED ME TO LEARN AS MUCH ABOUT CANCER AS A LAYMAN CAN..... AND THIS LEARNING PROCESS, WHICH BEGAN WHEN MY SON MICHAEL WAS TWO YEARS OLD AND CONTINUES TODAY, HAS LED ME TO SEVERAL CONCLUSIONS....SOME OF WHICH I WOULD LIKE TO SHARE WITH YOU TODAY.

THE MOST SUCCINT WAY I CAN FOCUS ON ONE OF THESE OBSERVATIONS IS TO RELATE TO YOU THE QUESTION ASKED DURING A PARENTS' CONFERENCE BY A CONGRESSIONAL AIDE:

"WHY ARE THE KIDS IN MASSACHUSETTS SURVIVING AND THE KIDS IN NORTHERN FLORIDA DYING FROM CANCER?"

WHILE THERE IS NO SINGLE ANSWER TO THAT UNDENIABLY TOUGH QUESTION, I FEEL IT CAN BEST BE SUMMARIZED IN ONE,UNDENIABLE NEED: THE NEED FOR A PEDIATRIC-ADOLESCENCE TUMOR REGISTRY.

YOU PROBABLY WONDER WHY A TUMOR REGISTRY ? WE ARE ALL FAMILIAR WITH THIS METHOD TO PRODUCE END-RESULT REPORTS. BUT WHY THE NEED DURING TREATMENT?

THE NATIONAL PARENTS' CONFERENCE BELEIVES, AS WE HOPE YOU WILL, THAT SUCH A SYSTEM WILL PROVIDE THE NECESSARY, TIMELY AND RELEVANT INFORMATION WHEN IT IS NEEDED...WHILE THE PATIENT IS BEING TREATED.

WE BELIEVE THIS WOULD GIVE THE DOCTORS TREATING CANCER PATIENTS THE INFORMATION THEY NEED TO HELP THEM DETERMINE THE BEST PROTOCOL FOR THE TYPE OF CANCER THEY ARE FACING.

WE ENVISION A REGISTRY TO INCLUDE THE FOLLOWING INFORMATION. WHILE THIS IS NOT INTENDED TO BE A FORMAL PRESENTATION OF A COMPLETE PEDIATRIC-ADOLESCENCE TUMOR REGISTRY, IT IS INTENDED TO BE A DRAFT FROM WHICH SUCH A SYSTEM COULD BE DEVELOPED:

* AGE, SEX AND PARENTAL BACKGROUND OF THE PATIENT, INCLUDING GEOGRAPHICAL LOCATION AT PRESENT AND GEOGRAPHICAL LOCATION WITHIN THE PAST TEN YEARS. MEDICAL HISTORY SHOULD BE INCLUDED.

* HOSPITAL WHERE TREATED. CLASSIFICATION AS A COMPREHENSIVE CANCER CENTER OR COMMUNITY HOSPITAL. NAMES OF DOCTORS INVOLVED.

* NUTRITIONAL INFORMATION INCLUDING BASIC DIET AND FAVORITE FOODS OF THE PATIENT AND FAMILY.

* INITIAL SITE OF SOLID TUMOR OR CANCER OF THE BLOOD.

* INITIAL TREATMENT ADMINISTERED. PROTOCOL FOLLOWED, INCLUDING ANY CHANGES AND WHY. THIS SHOULD INCLUDE THE RADIATION THERAPY USED, IF ANY, INCLUDING DOSAGE AND EXPOSURE.

* NEXT POSSIBLE SITE OF TUMOR; ADDITIONAL TREATMENT, IN DETAIL.

* TIMES BETWEEN FIRST AND SECOND INCIDENCE OF CANCER.

* PERSONAL OBSERVATION OF ATTITUDE, PERSONALITY OF PATIENT, FAMILY.

* END RESULT REPORT.

* FINAL REPORT, INCLUDING FINAL LOCATION OF ALL TUMORS AND A CLEAR

(CONTINUED)

DEFINITION OF THE CAUSE OF DEATH...WHETHER FROM CANCER ITSELF OR FROM RELATED CAUSES SUCH AS INFECTION OR UNCONTROLLED BLEEDING.

* THE REPORTS TO BE COMPILED ON A 6 MONTH, 12 MONTH, 18 MONTH AND 24 MONTH TIME FRAME.

THIS REGISTRY SHOULD BE ON LINE AS SOON AS POSSIBLE BUT WE ENVISION A LEAD TIME OF 24 MONTHS TO ALLOW TIME FOR THE NECESSARY STUDY AND ESSENTIAL WORK THAT WOULD BE NEEDED TO IMPLEMENT THIS IMPORTANT INFORMATION CENTER.

WE ALSO ENVISION THIS SYSTEM AS A NATIONAL INFORMATION BANK THAT ALL DOCTORS TREATING CANCER CAN CALL ON AT A MOMENT'S NOTICE. FOR THE COMPREHENSIVE CANCER CENTERS, THIS INFORMATION WOULD BE HELPFUL. FOR THE DOCTORS IN COMMUNITY HOSPITALS...AND MORE IMPORTANTLY FOR THEIR PATIENTS...THIS INFORMATION IS ESSENTIAL.

THANK YOU FOR YOUR KIND ATTENTION.

Thomas J. Byrne
172 Elm Street
Marlborough,MA 01752

Leonard D. Fenninger, M.D.
American Medical Association
Panel II
Clinical Applications and
Health Services Research

Clinical Applications and Health Care Research

New knowledge and technology which have been demonstrated to be of scientific merit and are applicable to various populations should become available in the diagnosis and treatment of illness and in its prevention at the earliest date compatible with safety, availability of persons with the requisite knowledge and skills and facilities and equipment necessary for their application. Dissemination of knowledge and technology is effectively accomplished through scientific publications, courses and meetings.

Support for the application of new knowledge and technology of proven usefulness is available from multiple sources. This support should continue. Developmental costs to apply new knowledge and technology in medical and other health care are appropriate expenditures for maintenance and health and medical care. They should be so recognized and included as part of the cost of providing medical and other health services.

Applications of new knowledge and technologies are always expensive. There are great pressures to divert resources from their development through fundamental research to their application. This has been particularly true in recent years when pressures have been exerted on scientists and technologists and the institutions in which they work to exert their efforts in practical applications of their scientific and technical findings and development and to diminish their efforts in fundamental scientific research.

Although the Federal Government has responsibility and interest in assisting in the application of new knowledge and technology related to the prevention, diagnosis and treatment of disease, this responsibility is most effective when it is shared through the use of multiple public and private resources and when the applications are as local as possible.

The Federal Government can encourage and foster cooperative efforts among the groups and individuals who have resources to bring to bear on problems of health and illness and should do so. It cannot and should not be the sole or even principal resource for the use of medical and other scientific knowledge and technology in improving the health and well-being of individual citizens. The Federal Government can play a more significant and useful function in using its limited discretionary resources in supporting fundamental research related to health and disease.

DR. JON V. STRAUMFJORD, JR. COLLEGE OF AMERICAN PATHOLOGISTS

TESTIMONY

NATIONAL CONFERENCE IN HEALTH RESEARCH PRINCIPLES

There are several practical principles I would like to add to the previous list and then discuss the need for an individual category of research:

1. The national support for health related activities has finite limits. When these limits are reached there is reasonable assurance that the highest priority will be given to health care delivery. When this occurs the support for basic research will be further eroded. Thus it seems prudent that consideration of research principles should include research programs directed to the curtailment of the health service costs.
2. If a major objective of our research is to provide not only the discovery of new basic knowledge, but to utilize the appropriate knowledge for public benefit we must consider that research represents an interlocked chain of activities from basic research through applied operations research and then finally to implementation. Weakness in any part of this chain compromises its application to the public welfare.

Since numerous individuals will be testifying in support of basic research and applied research, I would like to concentrate my comments on the need for operations research.

In the health care environment the lines separating applied and operations research is rather thin, however, they often require distinctly different personnel and much more in the way of team concepts. Operations research (management science) can be defined as the applications of methods of science to decision making in the management of complex systems of men, money, machines and materials. It is concerned with optimization or the selection of those alternative procedures that will lead to maximization of benefits while minimizing cost. For our purpose in health related activities we have to assume a broad concept of costs not merely monetary. The use of operations research is well known in industry, but unfortunately poorly applied to health care delivery. To my knowledge, our Pathology Department alone invests more monies in operations research in the clinical laboratory than the federal government. It is easy to imagine the need for operations research by merely following the complex pathway of a request for service through its completion and reporting in a University Hospital. We found that an average of 19 individuals were involved with a blood test from the time of ordering to the placement of the results in a patient's medical record.

Operations research can potentially provide enormous cost and quality benefits in health care with relatively little expense. Predictable gains can be achieved with the development of operations research programs within individual hospital departments. The greatest gains, however, are most apt to be achieved through the careful study of interdepartmental effects. The hospital's interrelationships are much like a Gordian knot, difficult to unravel. Change in one area of a hospital invariably influences other areas often unsuspected.

I would now like to cite several examples of operations research and its impact:

Examination of Hospital Administrative Services data indicates that the direct cost for laboratory services per admission when corrected for inflation, has actually decreased during 1970-1976. Depending upon the hospital size, the laboratory manhours per admission either decreased or stayed the same. Laboratory revenue per admission during the same period of time increased at a rate greater than inflation. The most dramatic change was a decrease of over 4 laboratory manhours per admission (from 12 lab manhours) in teaching hospitals during the years 1970 to 1976.

These changes occurred in spite of an average 50 percent increase in the number of tests per admission during the same time in the U.S. hospitals. Without such improved productivity, the direct expense per admission would have increased approximately 1 billion dollars between 1970 and 1976.

Superficial evaluation of these data would suggest that automation is responsible. There has been, however, little increase in the availability of automated equipment in the clinical laboratory during this period of time. Time studies indicate there is some improved productivity in newer versions of instrumentation produced between 1970 and 1975, but it was not significant. It is our belief that the major factor has been the development of productivity goals widely used by clinical laboratorians throughout the nation. The productivity goal is the College of American Pathologists Workload Recording System. The Workload System is based upon time studies of individual procedures and allows laboratory directors and laboratory personnel to compare their productivity with others.

We believe few individuals realize the remarkably improved productivity of clinical laboratories because health statisticians have been focusing on laboratory charges to patients not direct cost. Laboratory directors can influence cost, but generally have no control over the charge to patients for testing. Thus inappropriate regulations demanding correction by laboratory directors for something they cannot control could decrease productivity gains.

Another application of operations research is to assist us in the experimental design to ask the correct question. It is appropriate to ask whether federal and state policy is focusing on the correct question by requiring certificate-of-need statements for capital improvements and devices costing over one hundred thousand dollars which requires enormous effort for both providers and the state.

Examination of the data provided by the American Hospital Association in its Guide Issues indicates that the rate of increase in the expense per admission was essentially the same irrespective of the governance of the hospital. That is, the exponential rate of increase for federal hospitals was the same rate encountered in state, county, non-profit and for-profit hospitals. However, on an individual yearly basis, the largest cost per admission occurred in federal hospitals with the for-profit hospitals showing the least expense per admission.

Examination of similar data for the years 1972 through 1976 clearly indicate that the expense per admission shows essentially no significant correlation with percent occupancy. If over-bedding were a significant cause for escalating health care cost, there should be an inverse relationship between percent occupancy and expense. Incidently, we could find no published data to support the contention that an empty hospital bed costs over $25,000 per year.

High correlation, however, was obtained when comparing the payroll cost per admission (1975) to the total hospital cost per admission with payroll costs depending upon size, ownership and state ranging from approximately 50 percent to 60 percent of total cost. These data and data prepared by Hospital Administrative Services clearly indicate that the single most important factor in curtailing hospitalization costs is to improve the productivity of hospital employees. Furthermore, the measure of productivity represented by manhours expended per admission provides a useful comparative index of hospital efficiency.

If public policy continues to focus on the relatively small component of health care costs represented by capital improvements and instrumentation rather than productivity of individuals, spiralling costs are apt to continue. Furthermore, when the relatively larger group of individuals (war babies) increase in age they will be placing a greater demand upon our health care system. If policy does not change, and if we cannot secure an adequate data base to improve productivity, we are apt to face tremendous demand with outmoded facilities. Thus retaining outmoded hospital design by restricting capital funding can further increase cost by retarding or decreasing personnel productivity.

It is axiomatic that good medicine is cost effective. Good medicine implies a fast accurate diagnosis and appropriate therapy appropriately administered. Today's medicine is far more complex than just the interrelationship between a patient and his physician. Good medicine is facilitated by the acquisition of appropriate medical and scientific data. It is also facilitated by the same philosophy applied to the research and study of systems. Appropriate utilization of facilities can be encouraged by an optimum system designed for each setting. Requirements differ by region and level of care required. Such a system can be provided by the development of operations research programs by health professionals.

RECOMMENDATIONS:

1. Improve research capability for operations research by providing training in the philosophy and tools of operations research for existing health professionals.
2. Encourage and support professional organizations to embark on operations research programs and to accumulate appropriate data supportive of management research programs.
3. Encourage the development of operations research programs within medical schools. Furthermore, encourage medical schools to provide continuing education in health management research for professionals in all categories.
4. Provide visibility and acceptability by providing funding for operations research in major areas of health care.

Submitted by,

Jon V. Straumfjord, Jr., M.D., Ph.D.
Professor and Chairman
Director of Laboratories
Milwaukee County Medical Complex

ljh
9/29/78

Charles A. Walker, Ph.D.
Dean and Professor of Pharmacology
Representing the
INTERNATIONAL SOCIETY FOR CHRONOBIOLOGY

Several years of basic research have established predictable physiological and biochemical rhythmic patterns in animals and man. Diurnal variations in brain biogenic amines have been shown to occur and can be directly correlated with daily variations in behavior. Increased neuroenzyme activity and elevated concentrations of endogenous neurotransmitters stimulate the CNS during periods of increased motor activity, while the physiochemical mechanisms associated with the endogenous compounds classified as neuroinhibitors increase during the quiescent, inactive or sleep phase (Walker, 1969). Specifically, circadian patterns have been established for norepinephrine, dopamine, histamine, cyclic AMP, serotonin, glycine, GABA and the prostaglandins. Central nervous system drug responses are altered due to the time of day or night the dose is administered (Walker, 1972). The reproducible variations in drug toxicity, efficacy and effectiveness are directly correlated with the endogenous rhythms of several physiological parameters. Maximum changes in drug toxicity range from 20% for barbiturates to greater than 100% for the amphetamines (accutely aggregated animals). (Walker, 1972.) When treating and managing mental health problems, most practitioners are not cognizant of the role of chronopharmacology in altering the concentrations of neurotransmitters.

Clinical studies involving the antidepressants and antipsychotics, and their chronotherapeutic implications, are necessary for proper treatment of the several thousand schizophrenic and depressed patients.

It has been shown by Scheving and Halberg (1977) that by changing the time of day for the treatment of leukemic mice, the mortality rate changes by as much as 80%. Further studies showing biological rhythms in cell division, tumor growth and human carcinoma suggest the need for extensive future clinical investigations to determine the optimum time for drug administration to produce the most effective chemotherapy (Halberg, 1976).

The chronobiology of the autonomic nervous system has a significant impact on numerous peripheral cellular, tissue and organ responses (Walker, 1972). In humans the early morning, or immediately following rest in the case of nocturnal animals, is a period of "cholinergic dominance," which is the underlying mechanism for the increased G.I. tract responses, greater potential for bronchial constriction and asthmatic attacks. The increased vagal activity and decreased cardiovascular performance at this time can precipitate and amplify specific cardiovascular-related diseases. Certain types of cardiovascular deaths can be directly related to this time period. In the afternoon, near the end of the period of activity, is a time of "adrenergic takeover," which is probably due in part to increased adrenal gland activity. The peripheral autonomic responses during these periods are for the most part directly opposite. Drug dosing in the treatment of diseases for each period should be monitored closely and the concentration possibly modified for maximal effectiveness. Of tremendous importance during the period of high adrenergic activity is the implication of chronobiology in hypertension. (See Appendix 1: Chronobiology in Mesor Hypertension.)

Chronobiology, which includes chronopharmacology and chronotherapy, is an excellent potential contributor to better health care. Since many functions are rhythmic, quality clinical studies designed to articulate the optimum time to perform many of the life processes would result in a healthier society, with fewer diseases, fewer epidemics and decreased physiological health hazards. The proper practice and manipulation of chronobiology could serve as a significant tool in preventive medicine and the promotion of good health. The recognition and inclusion of chronobiology for all research and research principles involving animals, humans, the basic and clinical areas, is essential for greater relevance and accuracy in health care. Basic research designed for clinical application means very little if adjustments are not made for the chronobiological changes that are inherent for most animal functions (Knapp, 1978). Research involving animals and man in clinical pharmacology, pharmacokinetics, drug interactions, the pediatrics and the geriatrics, must include the changes due to endogenous biological rhythms.

In medicine, chronopharmacology and chronotherapy project a significant future in terms of decreasing drug toxicity, increasing drug safety, decreasing undesirable drug reactions and drug interactions, decreasing the total usage and total cost of medication, and maximizing the therapeutic impact.

The International Society for Chronobiology proposes that HEW provide formal recognition and strong support for chronobiology, because of the important role this area of science has played and its potential for establishing and maintaining quality health care.

We propose that an institute or study section for Chronobiology be established as a priority by the NIH.

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"The Rheumatic Diseases--A Major But Unappreciated Problem"

Hess
Panel 2

Mr. Chairman, my name is Evelyn Hess and I am McDonald Professor of Medicine and Director of the Division of Immunology of the Department of Medicine at the University of Cincinnati Medical Center. I am also the Director of the Arthritis Foundation Clinical Research Center and Project Director of the Ohio Arthritis Act Program at the Medical Center. Mine is a full-time academic appointment with responsibilities for research, teaching, patient care and unfortunately, some administration also! I would like to speak to you today on behalf of the 31.6 million people with arthritis of all kinds in the United States. I have endeavored to work for solutions of this major arthritis problem through my research, teaching and patient care and through my involvement in the American Rheumatism Association and the Arthritis Foundation at the local, national and international levels.

The patients I represent have diseases of the joints and musculoskeletal system attributed to, in a primary or secondary way, at least 110 different disorders. Many of these diseases have been defined within the last 50 years through careful, painstaking, clinical observation. Such observations, allied with basic research and clinical investigation, have allowed us to pin-point the cause in a very large number of the disorders. Unfortunately, the diseases which kill and disable the largest number of patients, rheumatoid arthritis, osteoarthritis and the other connective tissue disorders have not yet revealed their secrets. It should be noted that those disorders where we know the cause and therefore can apply specific therapy, have benefited from research in many disciplines. Examples include infectious arthritis which once caused such major disability, now cured by appropriate antibiotics, gout which also was a major crippler but benefited from research for anti-tumor agents in cancer, resulting in the uncovering of the role of enzyme xanthine oxidase in the uric acid pathway and the highly effective drug allopurinol.

These successes, resulting from basic research and a quick translation to clinical investigation and health service research have not yet helped the majority of our patients. These 27.5 million comprise 6.5 million patients with rheumatoid arthritis and 16 million with varying types of osteoarthritis as well as another 5 million with many kinds of arthritis including juvenile rheumatoid arthritis (about 250,000), systemic lupus erythematosus (about 1 million), systemic sclerosis, dermatomyositis, arthritis of the spine including low back problems and many other kinds of arthritis including the many types of bursitis. The number of arthritis victims in the National Center for Health Statistics 1976 Health Interview Survey revealed that 5,400,000 million of these arthritis patients suffer major disabilities. This represents a 54% increase from the 1969 survey. Estimates of the total economic impact of arthritis suggest a $13 billion figure. Add to this the $640,000,000 spent yearly on arthritis quakery and you realize that clinical investigation and health services research are a most urgent priority for this group of diseases (Appendix 1, the National Center for Health Statistics 1976 Health Interview Survey Data).

The rheumatic diseases lend themselves ideally to clinical investigation. Such research has successfully dissected out ankylosing spondylitis from rheumatoid arthritis, many metabolic causes for degenerative arthritis from primary osteoarthritis. These important clinical differences were frequently confirmed by the advantageous use of laboratory tests which in turn had resulted from basic research. Rheumatoid factors, LE cells, antinuclear tests, ASO titers and more recently HLA typing (B27 and the D locus) have helped us to define the seronegative arthritides, sub-groups of rheumatoid arthritis both adult and juvenile and have contributed greatly to the basic understanding of the immunogenetics of disease. We need to take greater advantage of this knowledge to define the populations at risk so that earlier diagnosis and better treatment can be provided.

We need also to take advantage of the advances in treatment resulting from pharmacological work with the nonsteroidal anti-inflammatory and other drugs. Different drugs result in different types of responses in different patients with rheumatoid arthritis posing the question of why this should be. Hopefully, we can with sophisticated clinical investigation, determine differing mechanisms of inflammation and patterns of response and even reverse the usual procedure and take the information back to the basic laboratory.

This area of health research urgently needs to take advantage of modern computer technology. With the recent availability of a uniform dictionary of rheumatic disease, these technologies could provide us with 1) comparability of clinical studies 2) facilitation of collaborative studies between Centers 3) development of a frame-work of teaching in rheumatic disease 4) establishment of a data base for clinical decision analysis 5) foundation for medical audit in rheumatic diseases 6) availability of accurate information on the epidemiology of rheumatic diseases and 7) improved patient care as a result of the above. These and other technologies should be made rapidly available for quick and efficient clinical trials of exciting new treatments when they become available. It is hoped that these would include surgical procedures as demonstrated so well by the studies of total hip replacement for arthritis in the United States.

It is manditory that we take advantage of the basic research and clinical investigation now available through the NIAMDD Arthritis Centers which resulted from the National Arthritis Act, the General Clinical Research Centers throughout the country which provide both in- and out-patient facilities for clinical investigation, the Arthritis Foundation Clinical Research Centers and the 80 Medical Schools which have Immunology and

Rheumatic Diseases Sections in their clinical science programs. The 31.5 million patients suffering from the many rheumatic disorders deserve no less than a total commitment for the next decade so that their numbers will be reduced and their disabilities easier to bear. Thank you.

STATEMENT ON BEHALF OF
THE AMERICAN ASSOCIATION OF COLLEGES OF OSTEOPATHIC MEDICINE
DR. A. KENNETH CIONGOLI

I would like to express my gratitude for being given the opportunity to appear and testify before this august body. I am Dr. A. Kenneth Ciongoli, a neurologist from Burlington, Vermont. I believe a brief summary of my background will be helpful in the understanding of my proposals. My medical degree is D.O., Doctor of Osteopathic Medicine, which I obtained at the Philadelphia College of Osteopathic Medicine after my baccalureate from the University of Pennsylvania. I then performed a rotating internship in the osteopathic profession. In 1968, I began four postgraduate training years at the University of Vermont College of Medicine and hospital, including one year of medicine and three years of neurology. This "defection" to the allopathic profession opened additional training doors; three months of neuropathology at the AFIP here in Washington, Neuroophthalmology at ME&E and eventually a Danish MS Society fellowship in Neuroimmunology at the University Hospital in Copenhagen. After approximately a year in wonderful, wonderful Copenhagen, I became a research associate in NI and Attending Neurologist at the University of Pennsylvania Medical College and HUP. Then, longing for the Green Mountains, I returned to Burlington, Vermont after 1½ years at Penn. The thrust of my research has been in the neuroimmunology of MS and other AI diseases of the CNS. I understand bench research, having spent more than 2 years in which 90% of my total effort was so directed.

From the perspective of a bench scientist and also a clinical neurologist, I would like to address Secretary Califano's initiative.

I agree completely with Sec. Califano that it is indeed sobering that federal support of basic science research has declined 19% in the past 10 years and also that there has been a serious backslide of our nation's research facilities. I was most dismayed to learn that there has been a 50% decrease in the funding of young scientific investigators.

I share Mr. Califano's judgment that the most basic principle must be to maintain at the highest possible level the federal government's support of fundamental research into biology and behavior.

I believe that he has correctly stated and aptly defended the need for research that is not immediately relevant and the need to actively incite the development of young innovators. I am sure there are others here today who will enhance these ideas, and I therefore would like to concentrate, in the remaining time, on what I consider to be a major problem area in our current research superstructure.

I am referring to the de facto segregation that has developed between basic science researchers and clinicians. In my career, I have been in both positions and I have shared the prejudices of both sides. Simply stated, basic science researchers seemed convinced that clinicians are overpaid, money-motivated and anti-intellectual. The clinicians have their opinions also. Laboratory based researches are considered to be on a free institutional-government ride, with intellectualism as their excuse. That one side or the other may be right is not as important as the consideration that greater than 90% of the lung tumors that are resected in this country never reach tissue culture, that greater than 90% of this country's multiple sclerosis patients and myasthenics are never studied immunologically and many other specific examples come to mind.

In spite of HEW's 3.4 billion dollars of research support, we have in this country a research superstructure, which ignores the primary physicians who control the research substrate, the patients.

Imagine a system in which every physician considered it part of his responsibility to take any active part in the expansion of the human fund of knowledge. How can we accomplish this?

I think that the multi-year strategy that Sec. Califano is currently planning should start with a restatement of physician responsibility. Every medical school graduate should consider it an integral part of their responsibility to be engaged in ongoing clinical research. Participation, in the sense of an understanding of research directions, and active communication with institutionally based basic scientists is necessary.

We should not expect these physicians to innovate research techniques, but we should expect the physicians to understand them. This is easily attainable by introducing these techniques in medical school and by incorporating them into post-graduate continuing medical education courses. As an example, it is my contention that, physicians will enthusiastically encourage their cancer or MS patients to submit to immunological evaluation, particularly if they understand mitogen stimulated lymphocyte proliferation, T and B suppressor and cell determinations, etc., and also if these determinations are free. Most important is to educate medical students that research participation is a part of their future responsibility.

The immediate benefits of such broadened participation would be many; improved patient morale and doctor-patient relationships, decreased lag time between multilaboratory corroboration of data, greater productivity of existing laboratories and thereby greater fecundity of the federal research dollar.

I would now like to call your attention to the osteopathic profession. Osteopathic physicians (D.O.'s) comprise 3% of this country's physician population, but care for approximately 10% of its patients. The explanation for this disproportion is that 75% of D.O.'s are primary care family physicians.

The basic science research effort of the profession to date has been small. The major cause of this has been the reluctance of federal government to fund the profession, a reluctance which was born in the political battle with organized allopathic medicine.

However, the profession is stronger than ever, with 14 osteopathic medical schools.

As I constructed my thoughts, it occurred to me that the current lack of a well-entrenched research superstructure is, at this time, a distinct advantage to osteopathic medicine.

The profession offers to HEW a competent, and extremely anxious infrastructure of medical teaching and care, ready to be built upon. The profession and the 10% of the American population for which it cares, sincerely hope that you will not ignore it.

STATEMENT ON BEHALF OF THE AMERICAN COLLEGE OF RADIOLOGY

by Ralph G. Robinson, M.D., Department of Diagnostic Radiology,
Kansas University Medical Center, Kansas City, Kansas, 66103 (For
Dr. James E. Youker).

I am Ralph G. Robinson, Associate Professor of Diagnostic Radiology and Head of the Division of Nuclear Medicine at the University of Kansas School of Medicine. I also serve as a member of the Advisory Committee on Radioactive Drugs of the Food and Drug Administration, most recently as Chairman of that Committee.

Today I am substituting for Dr. James Youker, representing the American College of Radiology. The American College of Radiology represents 12,500 of the 15,000 physicians in the practice of diagnostic radiology, radiation therapy, and nuclear medicine. Some 1,600 radiologists are currently filling academic positions, and are involved in the training of 3,200 residents in radiology, as well as allied health personnel in radiologic technology, radiation therapy, nuclear medicine and ultrasound.

Let me define the radiologist to you briefly, and then perhaps we can see why we have some of the problems we have in achieving adequate funding for the clinical application of our discipline: The diagnostic radiologist as a physician renders service to patients who are cared for by other physicians, and is therefore dependent on another physician's judgement and limited knowledge of radiology and its role in patient care before the patient is presented for a diagnostic or therapeutic procedure.

The radiologist has chosen to examine his patients from the inside-out, with X- and gamma rays, contrast media and radioactive drugs, rather than from the outside-in, in the manner of other medical practice. He is a user of high technology - but he understands that technology. He requires the assistance of basic scientists in physics, radiation biology, instrumentation, computer and pharmacy in his practice. He requires expensive capital equipment purchases, but he must have them because of the increase in diagnostic and therapeutic efficiency they provide.

Radiology is important - 7 of 10 Americans will receive a diagnostic X-Ray procedure each year. A recent study by Chamberlain indicated that 1/3 of all medical management decisions are made on information provided by diagnostic imaging in radiology or nuclear medicine. Radiation therapy is now used in part of the treatment regimen in 70% of cancer patients. One patient in three admitted to a hospital will undergo a diagnostic procedure utilizing radioisotopes. Yet, there is no focus for diagnostic radiology within the NIH. Why is this so?

I mentioned before that radiology is a discipline rather than a specialty in the usual sense. It does not identify with any one disease or condition, but rather is useful for all disease categories in all age groups. At a time when our technology is expanding at its greatest rate, the transfer of that technology has slowed to a near halt because of a sole preoccupation with purchase price. What then are our recommendations?

1. Provide a specific program for diagnostic radiology within an existing NIH institute.
2. Increase the number of diagnostic radiologists appointed to NIH study sections and national advisory councils.
3. Provide funds for research training in diagnostic radiology.
4. Consider funding a series of diagnostic radiology centers.
    a. High cost technology is involved - and the patient, who usually pays for captial equipment shouldn't pay for technology assessment.
    b. Proper cost, risk and diagnostic effectiveness can only be evaluated and cost effectiveness determined where the several diagnostic technologies are compared in a well equiped and staffed clinical environment.
    c. Risk-benefit could be evaluated more efficiently in such centers.
5. There is a need for further standardization and quality assurance in diagnostic and therapeutic radiology practice.
6. We need better radiopharmaceuticals and safer contrast agents to further improve our diagnostic sensitivity and specificity, in order to shorten the time-to-diagnosis, and therefore decrease hospital stay.

7. The emerging technology of emission computed tomography, using current radioactive drugs and positron emitters, needs to be recognized and separated from transaxial computed tomography in order that it may be evaluated without being confused with "CT" and denied installation and evaluation.
8. The cost of the several new technologies in diagnostic radiology requires that evaluation and transfer of that technology will have to be a shared responsibility of federal agencies, universities, and industry.

AMERICAN PSYCHOLOGICAL ASSOCIATION
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Oral Testimony Presented To

CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH PANEL
National Conference on Health Research Principles
U.S. Department of Health, Education, and Welfare

October 3, 1978

Presented by: Gary R. VandenBos, Ph.D.
Administrative Officer--Mental Health Policy
American Psychological Association

The American Psychological Association is pleased to participate in this conference refining the proposed DHEW health research principles. We commend the Department for its efforts in soliciting and incorporating commentary from a wide variety of organizations. The principles, and their implementation, will be strengthened by the inclusion of multiple perspectives, and by the ongoing collaboration of all involved parties.

In light of obvious time pressures, our comments will be brief. We support the one basic principle before this panel, namely, that to improve the quality of health care, reduce the cost of health care, and prevent disease and dyfunction, the health care system must support problem-oriented applied health research, in addition to fundamental research. I will comment on three matters pertaining to the implementation of such research support: 1) the role of the behavioral sciences in clinical applications and health services research, 2) the structure for the funding and administration of regulatory-related research, and 3) the standards for "high-cost, multi-year investigations and clinical trials."

The behavioral sciences are essential to comprehensive and high-quality health care delivery. While health care is based on medical knowledge, the delivery of health care is an interpersonal and organizational process, of which the effectiveness and efficiency is equally dependent on non-medical knowledge. The behavioral component of clinical applications and health services research includes such investigations as psychological factors related to medical compliance (or differential medical compliance with different treatment methods), the assessment of intented and unintented behavioral outcomes of medical interventions and related societal costs (based on differential return to full functioning and hence differential need for welfare support), and, even, behavioral treatments of physical health problems (as an alternative to surgical or pharmacological intervention).

Psychology is a resource to the health services research area. The research tradition in psychology is well-known. All psychologists, even clinicians, receive systematic research training as part of their core professional education. However, only considering research scientists, psychologists comprise eleven percent of such doctoral level scientists.

There is little doubt that health services regulatory agencies, generally lacking research components, need specific empirical knowledge, and systematic means of meeting these needs must be developed. We believe that these regulatory agencies should provide the funding for such mission-related applied research. However, we suggest that the highest quality of research and most efficient administration of such applied research might be through a research program jointly administered by the regulatory agency and a relevant research-oriented agency. Such a jointly administered program would facilitate access to the most appropriate group of researchers as well as to facilitate the quality and comprehensiveness of such research.

There is a clear need in clinical applications and health services research for investigations of long-term duration. The capacity to fund multi-year, high-cost investigations is critical. Such funding would obviously involve a significant percentage of federal health research dollars, and, as such, particular care must be taken to insure comprehensiveness and balance in our national research effort. In implementing such a funding strategy, we recommend that the standards for such high-funding/multi-year research grants or contracts include evidence that relevant behavioral investigators and perspectives were integral in planning the research effort. Frequently behavioral components are "tacked on" to research programs after the fact and are not integrated into the entire research program. All too often such investigations pay careful attention to the design, implementation and quality control that the biologic component of such research, but inadequate and naive attention to the psychological component of the research. When large funding is involved, priority for research concurrently examining medical and behavioral aspects, and separate concurrent peer review by a biomedical and by a behavioral panel would improve the quality of such research. We suggest that any program receiving over $150,000 in any one year, or receiving over $300,000 over a three-year period of time should be subject to additional scrutiny and greater comprehensiveness of research. Any program which commits a major percentage of public research dollars to a limited number of research centers on a long-term basis must be done with care, and attention must be given to insuring that all approaches are adequately and strongly represented.

PANEL: Clinical Applications and Health Services Research

Presentation

by

Roma E. Brown

Associate Professor & Chairman
Department of Medical Technology
University of Pennsylvania

Acting Executive Director
ASMT Education & Research Fund

STATEMENT

Submitted by

The American Society for Medical Technology

and

The ASMT Education and Research Fund, Inc.

American Society for Medical Technology
5555 West Loop South, Suite 200
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DHEW
National Conference on
Health Research Principles
4 October 1978

INTRODUCTION

The American Society for Medical Technology (ASMT) is a national professional organization composed of over 30,000 members engaged in education, research, and clinical laboratory services. Our membership is made up of a variety of nonphysician categories of clinical laboratory personnel including clinical laboratory administrators, supervisors, educators, technologists, technicians, assistants, and such specialists as microbiologists, clinical chemists, hematologists, immunohematologists, cytotechnologists, histotechnologists, and nuclear medicine technologists.

In addition to a membership diverse in specialty and generalist functions within the laboratory field, laboratory settings or places of employment range from private or independent laboratories to physician offices, clinics, blood banks, research institutes, to hospital laboratories -- both governmental and non-governmental. Thousands, in fact the majority, of our active members work in hospital laboratory settings throughout the country.

The ASMT Education and Research Fund, Inc., is a charitable scientific and educational organization whose services are provided to the entire profession of Medical Technology with approximately 170,000 in clinical laboratories in addition to those in educational and research institutions. A scholarship and research grants program, as well as educational services, is developed to enhance the scientific capabilities within the profession.

COMMENTS

On behalf of the clinical laboratory scientists that constitute the membership of the American Society for Medical Technology (ASMT) and the Trustees of the ASMT Education and Research Fund, Inc., I am pleased to present these comments regarding health research principles related to Clinical Applications and Health Services Research. This aspect of the research continuum, aimed at improving personal health services, is the essential link to bring to fruition extensive endeavors throughout the rest of the continuum. Research and projects aimed at clinical applications of fundamental research often lack glamour and spectacular perceptions and thus face difficult competition for funding. The emphasis in the draft principles on the impact of research funding on health services provided to our society is commended. These comments include support of the principle and concepts stated, some elaboration on the proposed statements, and additional concepts to be considered in the development of a context for formulating health research objectives and development of a conceptual framework for implementation.

The condition posed that basic research should be surrounded by, and relate closely to, applications research will certainly facilitate the translation of outcomes into services. The parsimony and synergism of this relationship, and the potential for influencing the focus of creative inquiry in fundamental research should be fully appreciated.

In the general principle stated for this focus (Clinical Applications and Health Services Research), a three-part goal was cited. An important fourth dimension should be added to this goal -- to optimize the effectiveness of the delivery system, from both the viewpoint of the organization and dynamics of the delivery system and the viewpoint of the patient's experiences and interactions with the system.

The first concept calls for strengthening all approaches to the solution of health problems. It may be implied, but it should be explicitly stated, that "all approaches" includes breadth in the type and perspective of the investigators. Non-physician health care professionals in the delivery system number over 2 million. The performance roles and knowledge base of these professions provide a unique perspective and potential in applied research -- and their incorporation in the evolving context and framework should be ensured. Let me cite two examples in the profession of medical technology to illustrate the potential.

The concept of quality control as a process to control laboratory error, which is now embodied in Federal regulations and private sector standards, was created by two medical technologists at the University of Minnesota. The classic work on the quality of water and its implications in technical errors was described, and standards set forth, by a medical technologist at the South Bend Medical Foundation. These two developments are among the most significant -- if not the most significant -- contributions to the improvement of the quality of laboratory results. Properly supported and fostered, the non-physician health professional, who focuses on a discrete body of knowledge at a depth not equalled by other components of the delivery system, has a unique clinical research perspective. The breadth of diagnostic and therapeutic services provided by these professions constitutes a range of services crucial to health care.

The second concept in the proposed draft poses the essential, but often omitted, final step of validation of changes. Considering the implications of diagnostic tests, as well as the costs, and the current debate on the potential contribution of broad screening programs, diagnostic regimens also require the scrutiny of validation. The attractive potential of preventive and early detection screening programs to reduce costs and morbidity should command a substantive commitment to characterize an optimal program.

Provision in the fourth concept for specific funding for clinical applications and health service research is essential to assure that this segment of the continuum is funded at a proper level and that all of the components mentioned are funded. The health service research activities should include not only personal services to patients, but also system considerations, such as integration of services, and environmental conditions, such as nosocomial infection problems.

Concept five which stipulates scientific merit as a condition of funding, and concept seven which specifies that the social value of anticipated findings should be the determining factor, may represent a conflict within the document. Certainly, scientific merit should be a predominant consideration; however, in light of statement three related to social value as a factor in prioritizing, the statement on scientific merit should be constructed to accommodate the full implementation of the remaining portions of the document. In setting priorities responsive to social values, it is important to consider the likelihood that research will test assumptions on which current policies and delivery practices are based, and will provide the basis for developing new options for health services delivery.

The last concept stated, which preserves the pluralistic approach to support funding within this focus, poses a challenge to the Federal agencies involved that is comparable to the health team concept that prevails in the delivery system -- a careful blending and balance among the agencies, each with an understanding and facilitation of the roles of the other agencies.

An additional concept is suggested as important to Clinical Applications and Health Services Research:

- Consortium investigations will be given priority consideration in those problem-oriented investigations that would be enhanced by study in more than one health care setting.

Thank you for the opportunity to present these comments. Both the American Society for Medical Technology and the ASMT Education and Research Fund, Inc., foster the conduct of applied research through their programs and activities.

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PEOPLE HELPING PEOPLE
AMYOTROPHIC
LATERAL SCLEROSIS SOCIETY
OF AMERICA

NTURA BOULEVARD, SUITE 315 • P.O. BOX 5951 • SHERMAN OAKS, CALIFORNIA 91403 • (213) 990-2151

Reply to: Elmer Cerin, Area Vice President, 5432 Connecticut Avenue, N.W. • Washington, D.C. 20015 • (202) 296-2380

STATEMENT BY THE AMYOTROPHIC LATERAL SCLEROSIS SOCIETY OF AMERICA TO THE PUBLIC FORUM HELD OCTOBER 3-4, 1978, AT THE NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES. FORUM HELD AT THE NATIONAL INSTITUTES OF HEALTH, BETHESDA, MARYLAND.

Amyotrophic lateral sclerosis (ALS) is a progressive paralytic disease in which the motor nerve cells of the nervous system cease functioning and sometimes die so that the muscles supplied by such nerve cells go out of control and become paralyzed, even stopping the breathing, swallowing and speaking functions.

- It usually strikes mature persons in the prime of life.
- Its cause is unknown.
- The average course is 3-4 years from diagnosis until death.
- Medical science has developed no therapeutic treatment.
- Until recently there was very little research specifically pointed toward ALS.

WHAT IS THE IMPACT OF ALS?

It has been estimated that there are between 10,000 and 30,000 cases of ALS at any one time. Because of the early termination of ALS patients, it is believed that ALS may well present an incidence as high as that of multiple sclerosis and four times that of muscular dystrophy, both of which diseases are receiving many times the research effort of ALS.

The impact on ALS patients and their families is devastating. To be told that one has a terminal disease, that his life will terminate within 3-4 short years, that the cause is unknown, that there is no treatment of therapeutic value, and that little is being done on AL by medical research, leaves the ALS patient small room for hope.

It is bad enough for the family and friends to see a loved mother, father, relative or friend struggle for life with the ever-encroaching and debilitating effects of ALS. It is, of course, worse for the patient. The anguish of watching a loved one gradually being devoured as the disease moves to its final victory decimates and demoralizes families. It usually bankrupts the patient family and creates a feeling of hopeless despair shared by patient and loved ones alike. There is no disease known to medical science that takes a greater toll both psychologically and spiritually. Considering the loss of productive and earning capacities, together with the cost of custodial and symptomatic care, the total cost of ALS to society may well exceed one billion dollars annually.

HOW WELL IS THE HEALTH CARE SYSTEM COPING WITH ALS?

While an effort is being made to find the etiology of ALS, the medical health team so necessary to extending the life span of the ALS patient, and so devoid of knowledge as to how to proceed, should be awakened to available treatments and techniques. The neurologist, general practitioner, pulmonary expert, nutritionist, physical and occupational therapists, and nursing professions must all be updated as to steps that can help the ALS patient to cope with the disease at every stage of its course.

The fact is that many ALS patients are left to cope for themselves after the first diagnosis and many more after the patient becomes bedridden and is unable to be attended in the doctor's office. We find that a high percentage of patients are left to cope with the disease on their own and/or with their families' unprofessional cooperation.

The rehabilitation factor for ALS patients is virtually non-existent because of the usually severe prognosis. The typical patient, as well as the medical team, accepts the verdict of death within a few years and of the uselessness of rehabilitative procedures. We believe that with continuing rehabilitative care, the life and wellbeing of the patient may be preserved for extended periods. It is up to the health teams to provide this care so necessary for the psychological and physical health of the patient. It is in this context that the clinical applications and health servicesresearch can become the important avenue to assist the medical health team in coping with ALS and possibly in slowing or even in stabilizing the course of the disease.

Thus far, clinical research on ALS has not been exhaustively pursued. The existing program has only been the recipient of relatively small amounts of money. Unless the funds are forthcoming, both from the federal budget and from private philanthropic sources, there will be little hope for developing preventive and rehabilitative measures. A few more million dollars for clinical research may well pay giant dividends in terms of life quality as well as economic savings for both our government and its patient citizens. Holding back clinical research funding from motor neuron disease (ALS) because of the lack of viable clues is now untenable.

The ALS Society in its three years of existance has funded over $1,000,000 in research. Until now, the Federal Government has not done much more than this in its efforts on ALS. Is it too much to ask for the Federal Government to allocate five or even ten times this amount for ALS Research?

The Congress in November 1977 recognized the destructive impact that ALS has and, accordingly, passed Senate Concurrent Resolution 26 which directs that national attention be focussed on the need to find a cure for this disease. The Congress has now supported the ALS research program by increasing the FY 1979 appropriations by some 50 percent, from a little over $2 million in FY 1978 to an estimated $3 million for FY 1979. The funding for NINCDS, overall, will also be increased substantially. The Senate-House conference is now meeting and it appears that the House allowance of $189 million and the Senate allowance of $225 million may yield an agreed-upon amount of some $210 million, an increase of almost $40 million over the FY 1978 appropriations of $171 million. In view of this substantial increase in available funds for basic and clinical research, it is recommended that for the current fiscal year NINCDS expand its clinical applications and health services research program for ALS and other neurological disorders.

Respectfully submitted,

Elmer Ceriń
Area Vice President

The Washington Home
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October 18, 1978

Mr. Kurt Habel
Chief, Program Planning Branch
D.P.A., O.P.P.E.
Office of the Director
National Institutes of Health
Building 1, Room 205
Bethesda Md. 20014

Subject: National Conference on Health Research Principles
October 3 - 4 1978
National Institutes of Health
Section Clinical Applications and Health Services Research

Dear Mr. Habel:

Dr. Edward Sheridan, a consultant to the Washington Home, was a participant in the National Conference on Health Research Principles, held October 3-4, 1978. He represented the Washington Home Hospice as well as Georgetown University. At his request we are submitting the following comments as an extension of his remarks.

As a health care provider the Washington Home is concerned about the direction that health services and research will take over the next several years. The Washington Home is a private, non-profit long term care facility which has been serving the metropolitan Washington, D.C. area since 1889. In July 1978 the Home in cooperation with Georgetown University's Vincent T. Lombardi Cancer Research Center and Group Hospitalization, Inc. opened a six-bed pilot hospice to provide for the terminally ill. The hospice has been established as a demonstration project to gather information on the actual operation of an in-patient hospice in an established long term care facility with third party reimbursement. It operates in conjunction with the Lombardi Center's Home Care Program.

Most of the health service and research over the past several decades have focused on prevention and treatment, with relatively little attention to those health care consumers who can no longer benefit from aggressive prevention or treatment techniques. Hospice care is designed to "ease the discomfort of the incurably ill and aged and to assure that when life must end, it does so with dignity." Although terminal care does contain elements of prevention , treatment and rehabilitation, the major emphasis is on comfort and care. The care and comfort components of terminal care are unique to this level of service and are not implicit in the prevention, treatment and rehabilitation continuum. Knowledge of the needs of the terminally ill and services to the terminally ill lag far behind and should, we think, have priority in planning a total health research program.

Much of the health care dollar is spent in providing care and services to health consumers who do not fall within the realm of preventive, curative or rehabilitative care, but could be described as chronic or terminal care. We suggest that the health research and service continuum be expanded to explicitly cover chronic and terminal care services. A health care continuum th at specifically includes chronic and terminal care components seems to be a more realistic portrayal of health care needs in this country. We encourage this expansion and recommend that research and service over the next five years work toward developing the chronic and terminal care phases of the health continuum. We would be pleased to explore these views with you at your convenience.

Sincerely,

David R Matlack

David R. Matlack
Executive Director

cc Dr. Sheridan

PANEL 3

HEALTH REGULATION AND PROMOTION

Environmental
Defense
Fund

1525 18th Street, NW, Washington, D.C. 20036 • 202/833-1484

September 29, 1978

COMMENTS OF THE ENVIRONMENTAL DEFENSE FUND AND THE NATURAL RESOURCE DEFENSE COUNCIL ON HEALTH REGULATION AND PROMOTION FOR THE NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

The Environmental Defense Fund is a not-for-profit national membership organization of over 46,000 lawyers, scientists, educators, and other concerned citizens working for scientifically sound solutions to our nation's environmental problems. For over ten years EDF has been actively involved in administrative, legislative, and judicial proceedings aimed at preventing human exposure to toxic chemicals. EDF has participated in regulatory proceedings before the Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), Food and Drug Administration (FDA), and the Consumer Product Safety Commission (CPSC). EDF has, therefore, had considerable experience with the interface between research and regulation.

At this time, EDF would like to submit brief comments for consideration by the Conference Panel on Health Regulation and Promotion. EDF intends to submit more detailed comments on the draft integrated Conference report, once it becomes available.

EDF makes the following recommendations:

1. The Department of Health, Education, and Welfare (DHEW) should dramatically increase funding for bioassays of the health effects of chemicals. Presently, DHEW does not support testing programs for neurotoxic, reproductive, or teratogenic effects. Established protocols exist for these bioassays and their cost is low compared to the per

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chemical cost of National Cancer Institute carcinogenesis bioassays.

EDF's experience indicates that manufacturers and users of chemicals do not sufficiently test for adverse health effects. And when testing does occur it often uses protocols which cannot realistically assess the risk of a chemical. Certain regulatory agencies such as CPSC, FDA and EPA do have authority, under certain conditions, to require manufacturers to test chemicals for health effects. Unfortunately, this authority is underutilized by the regulatory agencies. The resulting gaps in knowledge place the public at potential risk. DHEW must fill this testing gap and prevent public harm based on scientific ignorance.

EDF recommends that DHEW provide funds in the FY80 budget for assays for neurotoxic, reproductive and teratogenic effects of chemicals. Initial funding should provide for a minimum of 50 chemicals tested in each of the three assay areas.

2. DHEW should increase the size of its programs designed to verify bioassays for human health effects. In order for a protocol to withstand the legal scrutiny that attends all regulatory decisions, the number of false positive and false negative responses must be known and must be small in number. The strength of the Ames test and in vitro assay for cell transformation of hamster cells for identifying carcinogens, derives from the knowledge that false negatives and positives occur for less than 5% of compounds tested. Therefore, a regulatory agency can rely on either of these tests to support regulatory action.

Other protocols for assessing mutagenicity, carcinogencity, teratogenicity, neurotoxicity and reproductive hazards have not been as systematically verified as the Ames test. Programs aimed at verifying assays consist of running a series of known positive and known negative compounds in the assay. The percentage of false negatives and positives can therefore be determined.

NIH, by viewing its role as primarily oriented to basic or clinical research, has too often neglected this type of verification research. In addition, NIH has for too long constructed its research program based primarily on intrascientific concerns -- new research directions are aimed at answering questions that are raised internally by science as opposed to externally by society.

3. DHEW should provide a discretionary fund to the Director of NIH to fund high priority toxicological testing, the specific nature of which cannot be predicted during the zero-base budgeting process. In certain cases, the scientific literature will suggest that a chemical to which there is large public exposure poses a serious health risk. In order to follow-up on this initial study and determine the exact nature of the potential public health threat, follow-up studies are necessary. Currently, there is no routine mechanism at DHEW that provides funds for these studies. The result is that these studies are not done and public exposure to the chemcial continues.

The following is an example of this problem: In 1977, Food and Cosmetic Toxicology (volume 15, p.447) carried an article suggesting that a widely used hair dye ingredient was teratogenic in mice. While there were no obvious methodological faults with the study, the number of animals and doses used prevented final conclusions from being drawn. To EDF, this study raised the potential of a serious public health hazard. Over 35 million American women dye their hair. Many of these women are of child bearing age. The particular chemical studied is widely used in hair dyes and is structurally similar to all other major hair dye ingredients. EDF attempted to generate follow-up studies to verify the potential for harm. Previous industry studies on the teratogenicity of hair dye ingredients were methodologically deficient, so much so that it appeared that they were designed to find the safety of hair dye ingredients. FDA lacked the authority to require industry to test ingredients for safety and could not force industry to use accepted protocols in industry-funded studies. FDA itself did not have the resources to support the needed studies. The relevant institutes at NIH did not fund the needed studies. As a result, the studies have not been done. The discretionary fund herein recommended could have provided a mechanism for funding these studies.

EDF also recommends that a procedure be established for members of the public to request the Director to fund particular projects. The advisory board described in the following recommendation could provide part of this procedure.

4. DHEW should establish a series of advisory boards to the Director of NIH and the directors of relevant NIH institutes. These advisory boards should consist entirely of individuals who represent the interests of the general public. The advisory boards would participate in the institute budget making process and review an institute research plan. Creation of these boards would provide an ongoing mechanism for public participation in the research allocation decisions of the NIH.

The advisory boards should consist solely of consumers of health care and individuals with no financial stake in the research decisions of NIH. Membership should include representatives of labor, public interest environmental and health groups, consumer members of Health Systems Agencies, state and local health departments, and minorities. Compensation and staff assistance should be provided.

The advisory boards should be given an ongoing and substantive role in the budgetary decisions of NIH. Proposed budgets should be given to the advisory boards for comment early in the zero-base budgeting process, in time for the board to have a real impact on NIH decisions. The budgets should detail areas of intra- and extra-mural research projects and the rationale for budget allocations for particular types of experiments. The budget should be accompanied by a "Research Plan" for both the upcoming fiscal year and a longer range 5 year plan. The "Research Plan" should contain NIH's rationale for budget decisions for classes or areas of scientific research and a discussion of the health promotion and regulation impacts of these decisions. The "Research Plan" should be publicly available and notice of its availability indicated in the Federal Register.

The currently established Advisory Committee to the Director of NIH does not perform the tasks described herein. It consists not of individuals representative of the public but of institutions receiving NIH funds.

5. DHEW should establish a clearinghouse for information on ongoing toxicological research. The new publication "Tox Tips" achieves part of this goal but to our knowledge does not provide a cumulative listing of ongoing research projects. The needs of regulatory agencies do not follow the schedule of the scientific literature. A mechanism must be established for regulatory agencies and affected individuals to ascertain the nature of ongoing research into specific chemicals. This information will then enable these individuals to obtain the results of these experiments on an expedited schedule.

6. DHEW should dramatically increase its funding of public education materials on public health and specifically on the environmental causes of disease. The underlying scientific basis of a number of regulatory decisions is complex and has been exploited by industries to debunk the

need for regulatory action. Saccharin is the obvious example, but public misunderstanding of toxicological and public health principles have for too long stood in the way of regulatory progress in many areas. NIH, because of its reputation as the world's leading health research institution, is in a unique position to educate the public. DHEW should fund pamphlets, films, and classroom materials on the environmental and lifestyle causes of disease and steps the individual can take to reduce the risk of disease. Currently, the public is at the mercy of major industry advertising and public relations campaigns. For example, the Monsanto Corporation is spending over 10 million dollars for print and television advertising to rally the public behind the chemical industry and reduce public pressure for effective and necessary regulation. Obviously, the consumer community does not have the resources to match this industry commitment. Only the government can fill this role. Democratic decisions depend on the public having a full understanding of the issues. Industry supported advertising does not accomplish this basic goal.

7. DHEW must take a more active role in the government and in the press in support of regulatory decisions that affect health. DHEW is the nation's spokesman for health. It must actively interact in government decisions that affect health and convey its message and perspective to the American people.

An example of this sort of government outreach is provided by the Department of Energy. The Energy Department routinely takes public stands and fights the internal goverment battles relating to issues affecting its responsibilities. For example, Secretary Schlesinger attempted to play an active role in the Labor Department's attempt to set meaningful standards to protect beryllium workers. Secretary Califano should actively involve DHEW in certain energy department decisions -- for example, the health effects of developing alternative energy sources.

Actions by other government agencies that affect the health of the American population occur regularly. HEW should actively support a preventative health perspective in deliberations on these actions. This perspective should also be communicated to the general public through the media.

Respectfully submitted,

Leslie Dach

Leslie Dach
Science Associate

Maria Cleveland

Marcia Cleveland
Natural Resource Defense Council

This written testimony is made on the behalf of the National Council of Community Mental Health Centers. The National Council has, as its primary purpose, the establishment and maintenance of comprehensive community mental health programs in the United States. It is a membership organization that consists of Federally funded Community Mental Health Centers and other agencies that provide community mental health services. One of the primary interests of the National Council has been in the area of mental health research and program evaluation. It was based upon this interest, that I as Chairman of the Council on Research & Evaluation of the National Council, have been asked to prepare these written statements for your consideration.

1. Public attitudes towards mental health and mental illness are important variables for both the provision of direct clinical services and the development of prevention programs. It is suggested that our knowledge of how to effect these public attitudes is quite limited at the present time. Serious consideration needs to be given to the development of demonstration projects which will provide the field with reliable and effective methods to impact on the public through educational programs.
2. The existing state of knowledge of prevention in mental health is limited. There is a pressing need for government supported longitudinal demonstration projects that explore varied approaches to primary and secondary prevention in mental health. These projects should focus on developing methodologies and techniques that can be easily utilized by mental health agencies and practionners.
3. Health Service Agencies (HSA's) are assuming an increasingly important role. This fact is true for both health and mental health. However, the understanding and knowledge of HSA Board and staffs of mental health is often quite circumscribed. To assist HSA, demonstration projects designed to produce readily usable self-education tools should be implemented. The products of these suggested programs should aid in increasing general knowledge of mental

health and improving skills in mental health planning and utilization of evaluation data.

4. The provision of technical assistance to contract or grantee agencies is one of the most important tasks of government bureaus. At the present, there is, in mental health, an inadequate number of specialists in government agencies who are knowledgeable about research and evaluation and who are in a direct position to assist CMHC's and other providers. It is recommended that the number of specialists on this subject be increased and that their services be made more readily available to CMHC's.
5. What is the effectiveness and impact of the present methods of regulation and compliance monitoring of the Community Mental Health Center program? How does this process actually effect the delivery of services? These are important issues that require substantial investigation.
6. Financial arrangements frequently impact on the health care delivery system. This is especially true for mental health. It is suggested that attention be given to the impact of financial arrangements on the delivery of community mental health services.

It is our hope that the information provided to this panel will be of value in your deliberations on this important subject.

Prepared by:
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GOOD DAY MR. CHAIRMAN; MEMBERS OF THE PANEL; OTHER DISTINGUISHED GUESTS AND VISITORS:

MY NAME IS THOMAS J. BYRNE OF MASSACHUSETTS, REPRESENTING THE MASSACHUSETTS CHILDRENS' CANCER BLOOD PROGRAM AND THE CITIZENS COMMITTEE FOR THE CONQUEST OF CANCER, DENVER COLORADO.

I AM THE FATHER OF A NINE-YEAR OLD SON WHO HAS HAD CANCER. HE IS ONE OF THE FEW WHO HAS SURVIVED, THANKS LARGELY IN PART TO THE ADVANCES IN CANCER TREATMENT. MY PERSONAL INVOLVEMENT PROMOTED ME TO LEARN AS MUCH ABOUT CANCER AS A LAYMAN CAN..... AND THIS LEARNING PROCESS, WHICH BEGAN WHEN MY SON MICHAEL WAS TWO YEARS OLD AND CONTINUES TODAY, HAS LED ME TO SEVERAL CONCLUSIONS....SOME OF WHICH I WOULD LIKE TO SHARE WITH YOU TODAY.

DURING THIS QUEST FOR KNOWLEDGE CAME THE REALIZATION THAT BLOOD DONORS, WHILE ALWAYS NEEDED FOR THE CRITICALLY ILL, ARE NEEDED EVEN MORE BY THE VICTIMS OF CANCER. IN THE LAST DECADE THIS NEED HAS BEEN DOCUMENTED BEYOND QUESTION BY LEADING MEDICAL RESEARCHERS,CANCER SPECIALISTS AND SUCH PRESTIGIOUS ORGANIZATIONS AS THE AMERICAN CANCER SOCIETY.

THESE DONORS ARE NEEDED TO SUPPLY WHOLE BLOOD, BLOOD-CLOTTING PLATELETS AND HLA-TYPED WHITE CELLS. THE BLOOD TO RESTORE MASSIVE LOSSES....THE PLATELETS TO PREVENT INTERNAL BLEEDING AND THE WHITE CELLS TO PREVENT INFECTIONS: EACH OF THESE NEEDS ARE CAUSED BY THE NECESSARY BUT OFTEN DANGEROUS SIDE-EFFECTS OF MODERN,ACCEPTED DRUG, RADIATION AND RELATED TREATMENTS NEEDED BY CANCER PATIENTS.

(CONTINUED)

SCIENCE CANNOT PRODUCE....LABOROTORIES CANNOT DUPLICATE THIS BLOOD OR ANY OF ITS COMPONENTS. THEY ARE AVAILABLE FROM ONLY ONE SOURCE....THE HEALTHY DONOR.

BLOOD AND ITS COMPONENTS FROM THESE DONORS PROVIDE THE LIFELINE THAT CAN MEAN THE DIFFERENCE BETWEEN LIFE AND DEATH FOR MANY VICTIMS OF CANCER. IF WE CAN SUPPLY THE BLOOD AND COMPONENTS WHEN NEEDED, MANY PATIENTS WILL SURVIVE THE CRISES CAUSED BY TREATMENT...AND MANY OF THOSE WILL LIVE LONG ENOUGH TO ACCEPT THE FULL PROTOCOL NECESSARY TO CURE CANCER.

SINCE THESE OBSERVATIONS HAVE BEEN DOCUMENTED, WE MUST ASK OURSELVES WHAT IS MISSING. WE MUST LOOK AT THE NEARLY 400,000 PEOPLE EXPECTED TO DIE FROM CANCER THIS YEAR AND ASK OURSELVES: WHAT MUST WE DO?

FROM THESE OBSERVATIONS...FROM THESE DOCUMENTED FACTS...FROM THE STAGGERING DEATH TOLL MOUNTED EACH YEAR...I SAY WE MUST PROVIDE A NATIONAL BLOOD AND BLOOD COMPONENT DONORS' PROGRAM. I SEE THIS KIND OF PROGRAM AS ONE DEFINITIVE WAY OF ACTUALLY SAVING LIVES TODAY. THE LIVES OF FUTURE VICTIMS OF CANCER WILL HOPEFULLY BE SAVED BY EVEN MORE DRAMATIC BREAKTHROUGHS IN CANCER RESEARCH. I AM TALKING ABOUT THE VICTIMS OF CANCER THIS YEAR...THIS MONTH... TODAY.

I MUST ALSO NOTE THAT SUCH A PROGRAM WOULD HAVE SEVERAL BENEFICIAL SIDE-EFFECTS, INCLUDING THE CREATION, AT NO EXTRA COST, OF THE NECESSARY BLOOD-CLOTTING FACTOR NEEDED BY VICTIMS OF HEMOPHILIA.

(CONTINUED)

THIS FACTOR CAN BE OBTAINED IF WE HAVE ENOUGH DONORS OF PLATELETS. THE CREATION OF A NATIONWIDE,COMPUTERIZED BLOOD DONORS' PROGRAM, PROVIDING US WITH DONORS ON DEMAND, COULD ALSO VIRTUALLY ELIMINATE THE BLOOD SHORTAGES NOW SUFFERED DURING THE TROUBLESOME SUMMER VACATION AND HOLIDAY SEASONS.

I WILL SUPPLY YOU WITH COPIES OF RELEVANT, DOCUMENTED DATA WHICH SUPPORTS MY PLEA FOR SUCH A PROGRAM; BUT I WOULD LIKE TO LEAVE YOU TODAY WITH A QUOTE FROM ONE OF THE NATION'S LEADING CANCER SPECIALISTS, DR. ISAAC DJERASSI OF PHILADELPHIA'S MERCY HOSPITAL:

"CURES...ACTUAL CURES OF CANCER...ARE POSSIBLE WHENEVER PLATELETS AND WHITE CELLS ARE AVAILABLE ON DEMAND IN UNLIMITED QUANTITIES."

IF WE ARE LOOKING FOR A 'BOTTOM LINE' , LADIES AND GENTLEMEN, THIS IS IT. 'ACTUAL CURES' OF CANCER ARE AVAILABLE, IF WE CAN PROVIDE THE BLOOD COMPONENTS ON DEMAND THAT ARE NEEDED TO SUPPORT THE PATIENTS DURING CRISES.

AS THE FATHER OF A SON WHO WAS NEARLY LOST TO CANCER, I AM HERE TO PLEA FOR THE PROGRAM THAT WILL SUPPLY THE DONORS....THE DONORS WHO WILL SUPPLY THE COMPONENTS....THE COMPONENTS THAT WILL MAKE POSSIBLE THE CURES....THE CURES THAT WILL SAVE THE LIVES.

THANK YOU FOR YOUR KIND ATTENTION.

September 1978

HEALTH REGULATION AND PROMOTION

Testimony by:

Eugene Michels
Associate Executive Director of Communications
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Physical therapy is both a health care profession and a health care service essential to preventing, reducing, and overcoming problems of physical disability and pain. Attached to our written testimony are summary statements which describe the mission of physical therapy, the characteristics of physical therapy treatment and examination methods, and the characteristics of physical therapists germane to the focus of this session.

Overview of the Problem

Because of the relatively unique content and scope of its practice, and the emphasis in that practice on measuring and altering human performance, physical therapy has an important contribution to make to screening, prevention, and health educational programs. In fact, however, that contribution is now barely visible because so few physical therapists are engaged principally in these activities.

For the purpose of this panel session on Health Regulation and Promotion, we are concerned less with being left out of health promotion activities than we are with the validity of research into those activites given our low degree of current involvement in them. We can imagine that a few other non-physician health care professions share that concern. The "most effective" methods of providing preventive services and health education cannot logically be determined by research into only the limited models of health promotion which now exist.

The Solution

The solution to the problem we identify should be governed by the following principles:

1. Research into the relative effectiveness of various health promotion models should require that soundly conceived, contrasting alternatives be established on a pilot basis for the duration of a reasonable study period. These alternative models should be assured of a life span no longer than the study period, during which time they should not be obliged to become self-supporting.

2. Among the contrasting alternatives should be some consisting of various mixes of non-physician health care professionals, with and without participating physicians, in clinical settings with which appropriate faculty members and students in the professions affiliate. Screening, prevention, and health education, even on a pilot or experimental basis, should be given the opportunity of becoming a more central part of professional education.

3. The alternative models of health promotion should be supported to a degree which will attract experienced, highly skilled practitioners, including some with the necessary clinical research abilities, from the several

health care professions. The emphasis in limitation on funding should be more on the duration or life span of the models, and less on the ceiling during that life span.

4. Support should be given to devising and testing the effects of health education programs in which the government collaborates with the several health care professional associations. This collaboration may take several forms but its principal purpose should be one of joining resources to produce and test health education programs and materials on a scale of quantity and quality not now available.

# # #

Attachment

Richard L. Pharo, Sc.D. Eye Research Institute
Assistant to the President for Science

I am here to reinforce the urgent need to develop as an integral part of the national health research policy a nationwide program, involving both government and non-government agencies and institutions, in the promotion of health through public education concerning human health. Such a program, resulting in an informed public, will aid in developing health regulations that reflect the desires of an enlightened society.

Of the major factors impacting on humanity -- wars, religion, economics including taxes, etc. -- health is the least understood by the general public. Daily, the printed and electronic media pour out story after story concerning diseases and ways to both treat and prevent them. In most cases, however, these stories deal with the bizarre, the unusual, the sensational. Not enough is done in any concerted way by any public or private agency to conduct a coordinated public information program dealing with the current status of human health.

Although many factors are involved, sharing the responsibility for this deficit must certainly include both the professional health care delivery community, and the laboratory scientists. Both have seen fit through the years to avoid communicating to the public -- their patients, clients, friends and genuinely interested groups -- exactly what they know and have learned, in laymans language, about their particular area of health expertise. Reports abound of physicians who refuse to discuss health or disease with their patients. And this charge can be made against all fields of biomedicine. The assumptions have been that (1) the public is incapable of understanding, or uninterested in the subject of health, or (2) the professional community is not required to account for its activities.

The results of this lack of information have been manifold. First, holistic medicine, home remedies, quack practitioners, Eastern cultism, "nature" fadists and other attempts to find another way to health abound.

Secondly, the increase in physicians' office visits by people who really do not need medical care but seek it anyway is due at least in part to the "mysticism" of medicine that seems to promise a cure for anything and everything. A corrollary to this is the increase in liability cases against madical practitioners based on the assumption that if the physician did not cure the particular disease, it must have been negligence on the part of that physician, because medicine should be able to cure any disease.

Thirdly, the craving for more health information is demonstrated in a recent poll which showed that the interest of the general public in newspaper articles dealing with science and medicine is second only to articles on international affairs. Yet the newspapers can allocate only 4% of their news space to science.

Finally, and perhaps most importantly, the public has begun to demand more and more government intervantion in medical care delivery in three areas: (1) payment, (2) regulation of practitioners, and (3) increased regulation of "dangerous" substances, including drugs, foods, non-food chemicals, and materials that are demonstrated under any circumstances to impair health.

The public is saying, "We haven't gotten enough information about health. There must be more known than we have been told. We need to be protected from danger. Force the information from the medical community and 'protect' us with it."

The government has responded with a myriad of regulations on many aspects of biomedicine. Many of these controls are based not on scientific grounds, but on grounds that purport to reflect the societal ethics of our citizens. And although this reflection may be true in many cases, the assumption suffers from the fact that the ethics are often founded upon inaccurate and insufficient evidence to the public. The general public -- those who are requesting these regulations of health matters to protect them from harm -- very often arrive at their concern based upon information that hints at something, but which elicits only fears of the unknown. An outstanding example of this is the recent action taken by a government agency to place on their list of the most dangerous environmental contaminants a substance that is found in significant concentrations ubiquitously in plant materials such as wood and vegetables.

That these fears can be allayed through public information has been demonstrated in several instances. Some biomedical advances have stimulated new severe regulations; yet these regulations have been relaxed when the medical community has made the effort to provide a thorough public discussion of the matter. Recombinant DNA research is the most recent example of this reaction.

Much could be added about the need for more extensive dissemination of information obtained from biomedical research efforts. Accountability to the public trust, the potential of developing a negative environment for science such a Galileo faced, the potential for significantly reducing health care costs through an enlightened public, and the potential for reducing an ever-growing federal bureaucracy are some of the factors that must be given consideration in this matter.

We are proposing that a major part of the principle concerning health regulation and promotion be the encouragement of the biomedical research community, through adequate mechanisms and funding, to inform the general public in language and form that can be readily understood by the layman, about the progress being made in this most important area of human existence.

Everyone stands to gain from such a program. The biomedical community will be required to operate under only scientifically validated regulations. This will mean, among other things, that creative, innovative research, and the progress resulting therefrom, will continue to be a possibility. The general public will be able to implement a higher standard of health, with less anxiety about it, and at a lower cost, because they will have a better foundation of knowledge upon which to develop their medically-related life styles.

Jesse Roth, M.D., President-elect - American Society for Clinical Investigation

October 3, 1978

PANEL 3

HEALTH REGULATION AND PROMOTION

We are all committed to the goal of helping the federal regulatory agencies to protect the health and well-being of the public. On first inspection, it might then seem logical to provide these regulatory agencies with large scientific appendages to carry out research on problems that are perceived by the regulatory agencies to be of importance. My testimony is directed at raising serious concern and multiple cautions about undertaking such a program.

1. CREATIVE SCIENCE IN THE ENVIRONMENT OF A REGULATORY AGENCY -

We are committed to excellence in science. We all recognize that to thrive excellent science requires a special environment. The regulatory agencies have not in the past provided such a delicate sheltered climate. In fact, the overwhelming genuine demands of regulation may be inimical to science. Therefore, a heavy investment to establish a scientific research arm de novo appears to be very risky.

2. INVESTIGATOR-INITIATED RESEARCH -

There is widespread agreement that highest quality science comes from investigator-initiated projects. If the regulatory agencies wish to have laboratory scientists, it is to work on specific problems. This would clearly be directed research in its most precise form. Even if one wished in this case to support directed research, it would seem reasonable to avoid placing it in parochial isolation. It is clearly more reasonable to place the directed research within large broadly based free scientific environments.

Interestingly, investigator-initiated research has been the major source of new initiatives in this field. Most of the hazards that have come to the attention of the regulatory agencies for action, have been brought through the usual channels of science by investigators who have devoted their major efforts into one of these areas. Mostly these areas have not been foreseen as hazards by investigators who are outside of that particular area. Further, much of the follow-up work has been done zealously by those same investigators who were experts in the area.

3. OBJECTIVITY -

One of the great advantages that the regulatory agencies have had in evaluating the science has been their objectivity. They have been able to take all the available science, weigh it appropriately and use it within the framework of political realities. Clearly, science emanating directly from within one's regulatory agency would have unusual and special consideration. Objectivity would be impaired and inappropriate weight given to material that was generated internally. Even if objectivity was to survive, it would be difficult to convince outsiders that data from within were not being favored.

4. PRAGMATISM AND POLITICS -

Regulatory agencies, as part of their daily duties, must often consciously dissociate or at least widen the distance between science and government. For example, when the science is strong but the politics are unfavorable, the regulatory agencies may take a weak stand because government and the outside world are unprepared for a stringent approach. Alternatively, in the face of inadequate scientific data regulatory agencies must often decide promptly on a precise course of action. We are not here to fault this approach by our bretheren in the regulatory agencies -- this loosening of the bond between data and regulatory action. We only wish to point out that it is not a good backdrop for scientific research.

5. COMPETING PRIORITIES -

Can a government agency that has one overwhelming priority gain or retain additional independent priorities? Or will these new priorities with their budgets and their people be consumed by the main priority? The example of the armed forces is discouraging; they have all had recurrent unresolved long-term problems with biological research.

6. SUMMARY -

While we recognize that in regulatory action, politics overwhelms science, we are all committed to providing the regulatory agencies with excellent scientific information on which to proceed. We feel that this information is best generated in established, richly creative scientific environments with investigators who have made long-term commitments to these areas of research even before they became the foci of regulatory issues. We would strongly discourage the establishment of research laboratories directly within the regulatory agencies. If they were to be initiated, then very modest experimental units would be in order to see if they are viable. Epidemiology and related disciplines might be the best subjects for these early ventures. We urge that these early experimental ventures be kept very moderate until their worth has been established. Thank you.

Pediatric Pulmonary Association of America

"AIR AND LIGHT"
EVERY
CHILD'S
RIGHT

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I am Dr. Roy F. Goddard, President of the Pediatric Pulmonary Association of America. Along side of me is our Vice President and National Director, Mrs. Jacqueline Zaslow. We appreciate the opportunity to present our views before this panel.

We are concerned with the plight of more than ten million children in the U.S. today who suffer from varying forms of chronic respiratory diseases, ranging from allergies and asthma, with their severely debilitating effects to the more fatal, but less prevalent incidence of cystic fibrosis. Over the years, we have worked closely with the Department of HEW and with the Congress in order to bring about a comprehensive program of a multidisciplinary nature that would serve to alleviate some of the anguish surrounding this monumental problem. To a degree, we have been moderately successful, but we are now aware that many reforms and modifications are necessary, if this tremendous health threat to our youth is to be curbed.

We see the need for greatly improved coordination and interaction between the plethora of administering agencies within the HEW fabric, together with much stricter and more defined regulatory standards of implementation. Although the maintenance of high quality services, in research activities and in the delivery of health care, is of prime concern to us, we are much perturbed about the laxity in cost containment as it correlates to the apparent duplicative processes in federal funding. This appears to occur both on project and individual levels where a fragmented approach in fundemental and applied research emerges costly, without yielding optimum results.

Until now, there has been little substantive focus upon broad preventative measures; because of the swine flu scare, the public has become a little more attuned to the need for immunization; the Pap test has certainly lessened the mortality and morbidity menace imposed by cervical cancer. However, in the case of infants and children, and particularly those from disadvantaged areas, minority groups and rural regions, to say nothing of the silent majority of the middle classes, there exist practically no structured well rounded prevention and public education programs that address themselves to the early detection and possible elimination of pulmonary dysfunction.

The Pediatric Pulmonary Center Program, which I and some of my colleagues have fought hard to sustain over many years, does not begin to scratch the surface of the problem but five or six years ago, when there was virtually nothing, we felt it was a first step in the right direction. The program, whose thrust is rigidly restricted to training only, is currently authorized under Title V, Section 511 of the Social Security Act and is administered by the Washington office of Maternal and Child Health. Its funding level of approximately $2.5 million helps to support eleven centers in major medical schools.

Today, it is my belief that unless there were to be dramatic changes in the format and program philosophy, an appropriation of $10 million would not achieve the goals and objectives envisioned by the pioneers of this program, of which I am one. I am strongly convinced however, that if one totalled the number of dollars spent in the 1978 HEW budget by NIH, HSA and HRA on pediatric pulmonary disease oriented matters, one would come up with a very astounding sum. And sadly to my own knowledge, the fruits of many of these projects never see the light of day, but remain buried in the dusty archives of Bethesda and Rockville. By the same token, because there is no real mechanism for central review, it would be impossible to determine how many of these projects or studies are merely excercises in redundany rhetoric or apish caligraphy.

In trying to promote greater knowledge and a closer understanding of children's lung diseases, we have been privileged to work cooperatively with some of the key personnel of the Heart and Lung, Arthritis and Metabolic and Diabetes, Allergy and Infectious Disease Institutes. It has been a rewarding experience, to observe first hand, the kind of integrity and acumen displayed by these persons and their genuine concern to sponsor meritorious research only. But, under prevailing conditions, how can the distillation of their findings be transfused into a protocol that would serve the public interest?

In seeking answers to this dilemma, we consulted with Dr. Edward Martin of HSA, and he referred us to his ' Child Initiative Plan'. We studied this document and found nothing conclusive or relative to the points at issue, nor any ideology that would take into account possibilities for program expansion beyond the realm of his limited perception and scope of operation. Earlier in 1977, again in an effort to effect a self regulating system which would enforce uniform criteria for those concerned with the advancement of pediatric pneumonology, we offered constructive criticism on the national aspects of the program, and brought these to the attention of Dr. Martin. He then made commitments to study the situation,about which we have heard nothing since.

In support of our contentions, we completed a two year study, with myself and Mrs. Zaslow as the co-authors, entitled, "Children and Their Lungs". This opus, ironically enough was supported in part by a grant from MCHS. This time consuming survey, which covers the activities of the Pediatric Pulmonary Center Program and committent services available under the State Crippled Children's Services, gives a detailed breakdown of all such amenities, medically, demographically and socio-economically. In this paper, which incidentally, has since been reprinted by HEW, there were included several cogent recommendations, which had either been previously ratified or endorsed by the Association of Pediatric Pulmonary Centers, along with the approval and sanction of many prominent specialists in this field of medicine.

One of the important issues that emerged was the critical need for reliable data which would indicate the dimensions of the problem, and which also provide the means for *pin-pointing the weaknesses and lack of linkages* in the chain of operation. As far as we know, *these recommendations have been ignored* and there has been absolutely no effort made by *MCHS or HSA* to avail themselves of the expertize that made this program possible in the *first place*;and the subsequent refinements we suggested, that have now been incorporated into the program in a *quasi medical fashion* for the seeming purpose of generating more federal dollars into a *self perpetuating bureaucratic paper mill*. On behalf of the people, we object strenuously to these manoevers because *children are dying needlessly* at a *tremendously high and unnecessary cost to the American people.*

In light of this statement, we earnestly hope that once again, in taking the trouble to appear here today, we are not spinning our wheels in a futile effort

It would seem to us at this point, consideration might be given to the inauguration of a *'Child Health Bureau'*, where all the component parts previously cited, may have opportunity to be properly evaluated by a *consortium of peers*, and not be segregated by the attitudinal behaviour of those *endowed with administrative authority, but who lack perspective of public responsibility*.

Should the Secretary so desire, we will be pleased, within the October 20th deadline, to submit an interim outline of a blue print for the improvement of health care and research benefits that could be made available, in a realistic manner, to a maximum patient load at an equally realistic minimum of cost.

We are glad that our democracy still makes it possible to provide room for improvement, and we thank the volunteers of this panel for their involvement of time and for their concern in the improved health of the nation.

Albert F. Kelso, Ph.D.
Health Regulation and Promotion

**AMERICAN ASSOCIATION OF COLLEGES
OF OSTEOPATHIC MEDICINE**

4720 MONTGOMERY LANE, SUITE 609, WASHINGTON, D. C. 20014 301 — 654-5600

October 3, 1978

Drs. Eisenburg and Kandel
Members of Panel III
National Conference on Health
Research Principles

Gentlemen:

This statement from the American Association of Colleges of Osteopathic Medicine is in support of the general concept of a five year plan to guide HEW's health research efforts. Our fourteen colleges, their faculties and their professional staffs will cooperate in planning and implementing such a program.

In our statement on Principle IV we identified the problem that we need to convince each individual of their responsibility for their own health.

The Association believes that knowledge on health regulation and promotion will be a key factor in the future health of the Nation. We recognize that each citizen's health habits are the basis of personal and public health and any effort to change individual behavior will need to identify methods which are effective in establishing or changing life ~~through~~ styles of individuals through education. In addition the Association suggests that additional knowledge is needed on Federal involvement in bringing about the educational process.

It is generally recognized that personal habits have a direct effect on personal and public health. The goal of preventive medicine is to establish good health habits and to change habits which have created poor health or risks to health. We need knowledge on ways of obtaining the individuals attention, ways of developing self direction and identification of role models of healthy habits in order to accomplish this goal.

The Association believes that no single method will suffice to provide the citizens of the United States with this education. We need knowledge on the role of the home, schools, governments, media, and health providers in establishing the behaviors of individuals. In developing this knowledge specific attention should be given to use of institutions such as the home, school and health providers.

Drs. Eisenburg and Kandel
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The Association recognizes the need to study any method which influences individual citizen's life styles. We agree that the ends justifies the means in the case of creating good health. However, research on interventions such as regulations, state assistance or subsidy, use of media or provision of educational programs is needed to determine which are acceptable methods.

In conclusion, the American Association of Colleges of Osteopathic Medicine strongly endorses fundamental research on health principles, and supports the concept of research in preventive medicine.

Albert F Kelso, 10/3/78
Director of Research
Chicago College of
Osteopathic Medicine

STATEMENT ON BEHALF OF AMERICAN COLLEGE OF RADIOLOGY

by Otha W. Linton, director, Government Relations for Dr. James E. Youker

to PANEL 3 HEALTH Regulation and Promotion

The specialist in diagnostic or therapeutic radiology is subject to a large array of current and proposed federal regulatory and support programs, all of which fail to add up to a coherent and effective federal posture. Within the uses of ionizing radiation and other imaging modalities, are issues of medical effectiveness, health care costs, technology assessment, basic and applied research set upon the disciplines of radiation physics and radiobiology, concerns about public health hazards from radiation exposure and finally, issues of improving diagnostic and therapeutic techniques and results.

The Public Health Service has estimated that seven of every 10 Americans will receive a diagnostic x-ray procedure in any year. Some 70 percent of all cancer patients receive high energy radiation as part of their treatment.

Within the area of current concerns are federal programs dealing with

1. Evolving standards in clinical applications of medical imaging
    - A. A need to fund studies of what ACR terms "diagnostic efficacy" or the assessment of the imaging procedure upon the management and outcome of medical treatment. Each clinical imaging procedure stems from a clinical decision by a physician. Such decision making is subject to study and improvement with the payoff being reduced quantities of wasted procedures, wasted time, money and exposure.
    - B. With the development of a variety of diagnostic modalities, there is an opportunity to chose the optimal procedure, involving diagnostic x-ray, nuclear medicine, ultrasound or the new and exciting computed tomography.

C. Development of new and exotic high energy radiations suggest a time of change in the use of radiation for the treatment of cancer. Studies of biologic response to neutrons, pi mesons, electrons and such are vital to allow reasonable utilization of current capabilities. Likewise, studies of radiation potentiation and the integration of radiation [illegible] with surgical and medical modalities is now urgent.

2. Public health and screening uses of x-rays are developing outside of clinical settings and assessments.

A. Congress and DHEW have mandated chest x-ray examinations for coal miners, asbestos workers, coke oven workers and soon to be millions of others in dusty occupations. The principal objective is epidemiology and safety, rather than a direct health benefit to the individual.

B. Screening programs for people belived to be vulnerable to tuberculosis, women at risk for breast cancer and persons believed to be at abnormal risk to thyroid cancer have had public support and have created controversy. Besides their own merits, these controversies have cast confusion upon clinical uses of ionizing radiation.

3. Current congressional concerns about low level radiation exposures from occupational and military uses have spilled over into medical exposures, which do represent a major and deliberate source of exposure.

A. Most solid radiobiology is based kupon observations of high level radiation exposures at 100 rads or more.

B. Evidence at lower levels, such as those used in diagnostic radiology, is extrapolative and statistical and needs improvement in methodology and approach. More is known about low level radiation than about most other environmental agents, but much more is yet to be learned.

C. Improvements in radiation uses are dependent upon research support and vulnerable to unwise or overly zealous regulation.

  A. Developments like the CT scanner have reopened promise of much improvement in the quality and usefulness of images. By like token, dynamic imaging via ultrasound and nuclear methods is under intensive investigation.

  B. At the basic level, improvements in x-ray films, intensifying screens, generators, processors, tubes and other elements of the imaging chain make more likely the production of an acceptable image for every patient.

  C. Development of safer and more liable contrast media, injection equipment image intensifiers and image receptors promise better special procedures

  D. An increased investigation of information processing via automatic data handling and transmission systems offers much promise. Image transmission with high fidelity is now possible.

Presented by Stephen Gehlbach, M.D.

for

The Society of Teachers of Family Medicine

Introduction

The Society of Teachers of Family Medicine is comprised of approximately 1,440 members, all involved in Family Medicine education and training programs. It is an interdisciplinary society with members representing medicine, social work, education, pharmacy, administration, nursing, the behavioral and social sciences and other fields. Our members pursue their activities in medical schools, community hospital teaching programs, and community-based teaching practices. In the spring of 1978 the Research Committee of the Society was charged to review and articulate principles and strategies which might profitably govern the research effort of those in our discipline. That work began during the past summer and was accelerated in response to Secretary Califano's request for input into the development of a Federal strategy for supporting health research. The document presented here has been prepared by a task force of the Society and will be submitted to the organization's Board of Directors at its next meeting in October 1978. Many of the members who are involved in research also participate in the North American Primary Care Research Group. This testimony is a joint effort of these two organizations.

FOCUS 3: HEALTH REGULATION AND PROMOTION

We are committed to the concept of health promotion. Preventive medicine has always seemed to us to be a more humane, cost effective approach to medical care than emphasizing repair and remediation. We would like to offer three research goals to operationalize the theme of health promotion:

1. Development of new preventive health and screening techniques.

2. Critical evaluation of established procedures.

3. More effective methods of implementing established health promotion methods.

Developing New Techniques

The biologic and technologic advances of recent years have greatly enhanced our potential for promoting health. We can screen for genetic diseases like phenylketonuria and congential hypothyroidism. We can find cancer in presympotomatic stages. We can detect absorption of lead and other toxic metals, and we can offer protective immunization against a host of infectious diseases. We need now to turn our attention to creating a preventive medicine for the common problems associated with the stresses of twentieth century living. Having conquered polio, and tetanus in our children we must look toward the behavior problems which bring scores of anxious parents to offices of pediatricians and family physicians each year. Adequate health promotion means developing preventive interventions for school adjustment problems, learning disabilities and hyperactivity. It means preventive problems of adolescent adjustment, teenage pregnancy, and drug abuse.

To date we have been unsuccessful in promoting the health of families. Divorce is epidemic; so is alcoholism; depression occurs in up to 30% of "average" outpatients. We know little of how to promote smooth transitions through the life crisis of adulthood and old age. All these areas are ripe for development of health maintenance and health prevention strategies.

Support for interdisciplinary research utilizing behavioral scientists and primary care physicians is a beginning toward solving some of these problems.

Promoting better health in the workplace and reducing hazards of the environment is another area in which family medicine shares a research role. Together with the epidemiologists we need to explore more effective techniques of identifiying patients who are at risk for the chronic diseases produced by occupational exposures. Often it is the primary care, family physician who has most ready access to patients exposed to asbestos, pesticides or cotton dust. The family practice setting is also an ideal arena for assessing the impact of environmental pollutants on patients with chronic bronchitis, emphysema, and asthma. Acquisition of community based data is essential for enacting meaningful regulations to improve our environment.

Developing effective health promotion measures means improving methods of communicating information to the public. The overall experience with health education programs in this country is far from encouraging. Studies suggest that the physicians' office is a potentially effective but underutilized arena for health education. However we must improve on the traditional bland health brochures and uninspired physician sermons if we expect to make a substantial change in the health behavior of the country.

Evaluating Established Techniques

A second research priority is the critical assessment of currently practiced preventive medicine methods. Despite the advanced technology we have at hand, it remains unclear whether many of the health maintenance and screening measures currently practiced are truly efficacious. We feel confident that screening for PKU can prevent the devastating social cost of one type of mental retardation. But we don't know the value of the time honored annual physical examination. Most would agree on the benefits of routine childhood immunizations, but there is great debate surrounding the frequency with which we need to perform pap smears. How much health is promoted by routine prenatal care? How much by attaching women in labor to fetal monitors? Do the advantages of early identification of latent diabetics or the genetic carriers of sickle cell disease outweigh the psychological damage of labelling these patients? Our information is incomplete. A logical place to pursue answers is in the setting of family medicine.

Devising New Methods for Implementing Health Promotion Strategies.

The final research task facing preventive medicine is creation of better means of modifying risk-taking behavior. Having successfully identified major causes of morbidity and mortality in our country, we remain relatively powerless to influence their prevelance in the population. Obesity, tobacco abuse, alcoholism and mortality from automobile accidents have shown little response to our professional efforts to reduce them. Vast sums of money have been expended in an attempt to protect automobile passengers who steadfastly refuse to employ the simple strategy of fastening a seat belt around themselves or their children. We've been unable to alter the eating habits that have created a national catastrophe of caloric excess. Communication techniques for health promotion must be devised that rival the success of those that have placed sugar-coated nutritional nonsense on every American breakfast table.

In summary, we see Family Medicine as a vital research stage for addressing issues of health promotion.

We urge support for:

1. The development of new behavior oriented preventive medicine techniques.

2. The reassessment and evaluation of currently practiced health promotion methods.

3. Development of more effective means of implementing health promotion strategies.

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Testimony Before The Panel on Health Regulation and Promotion

National Conference on Health Research Principles, October 3, 1978

Presented by: Joan S. Zaro, Ph.D.
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The development of health research principles in the areas of health regulation and promotion take on particular significance since policy and regulatory decisions will be made with or without an adequate knowledge base. These decisions have far-reaching long-term consequences. It is extremely important that an adequate knowledge base be developed rapidly in order for these decisions to be made in an objective and well-founded manner as is possible. We support the general proposed principles which have been developed in advance of this conference. In my testimony I will amplify and focus on areas related to mental and behavorial health in which we, as a psychological association, have most to contribute.

Psychology and the other behavioral sciences are developing a significant and rapidly growing knowledge base in the area of behavioral medicine which deserves recognition and support by the Department. It promises to provide critical assistance in the amelioration of many of our country's major health problems. The health of a society at large is not dependent solely as it once was thought upon medical advances in the treatment of illness. It is becoming more and more clear that individual and group behavior has a great and direct impact upon health, more in fact than do huge expenditures for medical treatments.

Some reasonable allocation of resources must be made between research on the treatment of illness and behavioral research which will generate information relating to how to develop and enforce regulatory decisions resulting in more healthy lives. To date our government has primarily funded illness research, which, given our increasing knowledge about how critical behaviors, lifestyles, and compliance with treatment regimens are, will no longer best serve the public's health. Alcohol, drug, and other substance abuse problems and their ramifications are major societal health problems, as are large numbers of other stress-related disorders. More knowledge should be generated regarding the relationship between stress-producing environments and health, how to reduce the anxieties and pressures of everyday life which lead to health problems, and how to increase the individual's abilities to cope effectively with such stressors a complex and rapidly-changing society.

Another area of concern is the issue of the generation of new treatments for behavioral disorders and the determination of their effectiveness. The scientific bases for regulatory decisions in these areas are at this point extremely scarce. One of our most serious and fundamental problems is the lack of basic knowledge in what currently exists, that is, the needs/demands of the population, where, how, and by whom individuals are being treated, and what are the effectiveness/outcomes/cost efficiency of these treatments. These are research areas which are critical to be explored more thoroughly and which will provide invaluable information for regulatory decisions. We urge strongly that the Department support the efforts of the professions and others in the development of a knowledge base related to the evaluation of treatment outcome and treatment effectiveness. This includes the application of well established psychotherapeutic techniques to new health-related problems and particularly the variety of emerging techniques based on principles of learning such as behavioral control, pain management, and biofeedback techniques.

We also strongly urge support by the Department of the regulatory efforts of the profession themselves. The professions have a long history of efforts at self-regulation, including setting credentialing standards, developing accreditation systems to ensure quality education and training of providers, and developing ethical codes and standards of practice which govern the activities of their members. Rather than have the federal government duplicate such efforts, it would seem most cost effective for the Department to support further development of these and other regulatory efforts on behalf of the professions.

We also strongly support the proposed research principle that interdisciplinary cooperative efforts be encouraged. It is quite clear that the medical profession alone cannot handle the problems associated with health and health maintenance in our country. It simply does not possess the necessary expertise. For example, in the areas of alcoholism and obesity, behavioral scientists have demonstrated leadership in developing a knowledge base and treatments which have had a significant impact upon these problems. It would be our hope that this Panel and the Conference as a whole will endorse the basic philosophy of equal support for both biomedical and behavioral research in health, health regulation, and health promotion.

Finally, the areas of health prevention/promotion are two of the most troublesome and least understood. There are some basic definitions which need to be reached before progress can be made in developing fundamental knowledge relative to these areas. For example, it is not yet clear what we all mean by the term "health". It would be critical for the Department to define what is a healthy person, and what, societally speaking, are indices of health so that it is possible to evaluate whether efforts at prevention or health promotion are effective. Again, one must define the goal clearly and first develop basic knowledge regarding the actual incidence or risk in the population. Otherwise, we will be unable to evaluate whether regulatory and preventive efforts have been successful. This is particularly critical in the mental health fields.

Again, we strongly urge a major research effort in the area of prevention and health promotion. Behavioral scientists have a great deal to offer in the area of prevention since much has to do with development of an adequate knowledge base, promotion of healthful life styles, and consumer education regarding health-promoting behaviors. As yet, we have very little substantive knowledge about what works in prevention, and major research funding should be diverted from long-standing medical/illness priorities to bolster research efforts in this area, particularly with children. It is our opinion that we as a society need to reorder our priorities of health care to assure the broadest impact on improving and maintaining the general health of the consumer rather than to emphasize the treatment of illness after it occurs.

I thank the Panel for the opportunity to make this presentation, and wish you success in your efforts.

STATEMENT ON BEHALF OF THE AMERICAN COLLEGE OF LEGAL MEDICINE

The American College of Legal Medicine (ACLM) is comprised of professionals with degrees in medicine and law, or with a degree in either medicine or law and an interest in the other discipline. Its members practice their profession, work for various governmental agencies (eg, the Armed Forces Institute of Pathology, Food and Drug Administration, Veterans Administration), advise businesses as insurance companies and pharmaceutical firms, or function in an administratice capacity as hospital directors, members of healing arts licensing boards or the like.

The purpose of the ACLM is to further research and education in the area of problems at the interface of law and medicine. Perhaps foremost among these problems are those relating to medical jurispruidence - the impact of laws and legal processes on the practice of medicine - which includes both statutory and case law as well as administrative regulations. In the field of medical research there is little case law at the present time. The requirements for obtaining informed consent from research subjects are well known examples of administrative regulations in medical practice, however.

During the past decade legislative efforts have been directed toward consideration and enactment of statutes dealing with biomedical and bioethical subjects. The Uniform Anatomic Gifts Act is a well written model law that has shown great potential for furthering medical research and health care.

Drafted to fulfill a specific need, this Act is now law in all but one U.S. jurisdiction. It exemplifies the end product of combined experts from both law and medicine, and will contribute immeasurably toward helping the law keep abreast with medical advances.

More recently the Conference of Commissioners on Uniform State Laws and individual legislatures have addressed themselves to statutory drafting on biothical subjects as "the Definition of Death," "the Living Will," "Do Not Resiscitate," and similar topics. While there unquestionably may be a need for such legislation, it is essential that all acts in this area be carefully conceived and meticulously drafted, to protect not only individual, family and public interests but the long term interests of health care - its immediate delivery and future advances.

The American College of Legal Medicine is deeply concerned that some of these individual state statutes or model acts may be drafted too hastily, without thorough input from experts knowledgable in both law and medicine. The intended salutory effect of such a statute may in consequence be lost; medical research and care may be set back; and individual or other interests may be neglected.

There is within the membership of the American College of Legal Medicine considerable expertise for recognizing and resolving problems at the interface of law and medicine. The Board of Governors of the College urges that efforts at drafting individual and model legislation be held in abeyance until full medical legal expertise can be brought to bear on the drafting process. The Board offers the services of the College to all health care oriented agencies and organizations, as the Department of Health, Education and Welfare, to all agencies concerned with the drafting of such legislation, as legislatures and the Conference of Commissioners on Uniform State Laws, and to other interested parties to assist in the drafting of model acts in the bioethical and biomedical area. The president of the College, Richard F. Gibbs, M.D., J.D. has appointed a task force to this end.

William H. L. Dornette, M.D., J.D.
President Elect, American College
of Legal Medicine

UNITED STATES PHARMACOPEIA

Remarks to the National Conference on Health Research Principles
Health Regulation and Promotion Panel
Bethesda, Maryland, October 3-4, 1978

by William M. Heller, Ph.D.
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My message is pure and simple: the health professions are blessed with a high proportion of concerned citizens dedicated to helping sick people get well and well people staying well; therefore, the research focusing on health regulation and promotion should take into account the fact that this reservoir of motivated and knowledgeable public servants exists. I use the term "public servants" in the old-fashioned pre-bureaucratic sense of private citizens who have chosen life-careers in the service of their fellowman. Just as there is no substitute for an adequately compensated, job-secure bureaucrat to do some jobs, there is no substitute in other instances for the volunteers and their organizations who know the target area from being workers therein.

Volunteers as individuals and as groups in professional societies are an endangered species, judging by the tone of the preliminary and secondary documents of this conference. These documents speak of government bureaucracies helping each other, and investigators, and the public. There is barely mention of voluntary organizations and the multiplier effects they can bring to health research and the dissemination of results.

Their endangerment is already too frequently embodied in proposed legislation and regulations.

Take, for instance, the Drug Regulation Reform Act of 1978. It calls for a federal compendium of FDA-approved prescribing information for every marketed drug.

The pluralistic drug information system now available to prescribers might well be put out of business by a federal compendium. The AMA-Drug Evaluations of the American Medical Association, the American Hospital Formulary Service of the American Society of Hospital Pharmacists, and the Handbook of Nonprescription Drugs and the Evaluations of Drug Inter-Actions of the American Pharmaceutical Association -- all produced by volunteers, with a financial commitment to a supporting secretariat by their respective professional associations -- might be sacrificed by a free federal compendium, not to mention the sacrifice of professional judgment when faced by the implication that whatever a federal compendium says had better be followed because it's the government saying it. For that matter, a book of FDA-approved prescribing information already exists, the Physicians Desk Reference. It has government-approved prescribing information for all of the drugs any owner-manufacturer believes are worth paying PDR to print and distribute. It is available free to practically all prescribers, at no cost to the taxpayer, and is available at a very nominal price to anyone else, including patients. If PDR contains practically all of the drugs anyone is really interested in, what is it worth to print and distribute information about the thousands more that practically no one is interested in? And at the cost of financially endangering the volunteer efforts of the professional societies? What is it worth to gain a monolithic drug information system for the balanced and complementary drug information services available through the services of dedicated volunteers supported by their professional societies (not to mention some good for-profit drug information services whose user-value is attested by the fact that they do make a profit)?

The proposed Drug Regulation Reform Act of 1978 contains a requirement for Patient Package Inserts (PPI). Like the labeling for prescribers, the language of the PPI would be negotiated between the manufacturer and the regulatory agency. Just as the package insert for physicians has become more of an adversary scrap between lawyers than an informative piece of paper for prescribers, PPI prepared in that context would likely be sunk with the information-overload of defensive labeling.

It was not always thus. When the first Food and Drug Act was passed in 1906, the government recognized the United States Pharmacopeia and the National Formulary as the official compendia of standards of strength, quality, and purity. These official compendia are produced by a non-governmental organization, the United States Pharmacopeial Convention. When one considers that strength, quality, and purity were the only aspects of drugs over which regulatory enforcement was then authorized, this dependence on non-governmental volunteers becomes even more remarkable. The system still works today, after 72 years.

The Pharmacopeial Convention is the nation's only national network of physicians and pharmacists dedicated to a broad public task in the regulatory area. Short of this, there are numerous special boards, committees, and commissions of volunteers that advise in or participate in regulatory affairs at state and national levels. Health researchers should keep them in mind as they test strategies to promote health by regulatory and promotional means.

* * * *

Comments on Health Research Principles Before Panel on Health Regulation and Promotion [1]

Franklin E. Mirer[2], Ph. D.
Industrial Hygiene Consultant
Social Security Department
International Union, UAW

Although UAW Representatives have spoken before on Biomedical Research Policy, it always seems necessary to justify why a labor union feels impelled to make such comments, and why scientists should give weight to these opinions in their deliberations.

The UAW is the representative of over 1.5 million members, and as such bargains for the health insurance coverage of over 5 million workers and their families. Therefore, it is concerned about the cost of these plans. As a party to these major health insurance plans, the UAW sits on numerous boards of administration of health care agencies and programs. As the legislative representative of its members, the UAW has participated for years in efforts at governmental reform of the health care system at the national and local level; these efforts are not limited to the campaign for National Health Insurance. Finally, the social and political thinking of the

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[1] National Conference on Health Research Principles, National Institutes of Health, Bethesda, Maryland, October 3-4, 1978.

[2] 8000 East Jefferson Avenue, Detroit, Michigan 48214

Union leads it to place great weight on policies which will improve the health and well-being of not just our members but the great majority of the people of this country.

The UAW has learned that the improvement of the health of the American people depends on the functioning of a complete health care system. It has also learned that research laboratories are just as much a part of the health care system as operating rooms or doctors' offices, that the research component of the health care system is the source of advances and must be nurtured as much or more than any other aspect. The UAW also has on its staff health professionals with expertise in health administration, occupational and environmental health, and therefore has a foot in the camp of both the consumers and the professionals.

A starting point in this discussion is that the main improvements in the health of Americans will come from advances in the prevention of disease, not treatment, that progress in this area depends on research advances, and therefore research policy must take this into account. Within the area of preventive programs, high priority ought to be given to the problems related to occupational and environmental health. These remarks are addressed to the panel on regulation because research will contribute to preventive medicine by informing regulation.

1. The fruits of research related to disease prevention are likely not to involve medical professionals.

Scientists must guard against the tendency to allow our experience with fee-for-service medical treatment to direct our thinking toward fee-for-service prevention. The plan of most preventive medical programs consists only of going to see the physician before the patient is sick, rather than after. The most important preventive work may not involve physicians at all.

Take the famous historical example of the work of Dr. John Snow during the 1854 London Cholera epidemic. Medical diagnosis and the beginnings of epidemiology, elegant and advanced scientific work, identified the source of contagion. However, Snow's preventive work was not in medical practice -- it was as an apprentice plumber, when he removed a pump handle from the contaminated water system. And today, despite advances in immunization techniques and antibiotics, physicians play only a back-up role in Cholera prevention.

This paradigm should inform our thinking our environmental or occupational disease. Early detection of environmental cancer or precancerous conditions -- presumably a physician's role -- is at best secondary prevention. Research should direct itself at detecting the cancer-causing agents and preventing exposure. While clinical research, and scientific or medical professionals are the key to detecting environmental disease risks, the response to these risks need not directly involve the specialties which detected them.

2. In occupational health, regulations are needed if scientists are to be able to do research.

In analogy with infectious disease, in the modern epidemic of environmental and occupationally induced disease, the carrier of the agent is the environment, often the industrial environment. Research and surveillance must work hand in hand. Documentation of disease cases and evidence regarding effects of chemicals becomes important public knowledge, even if it is in private hands. This principle, well accepted in traditional public health has been resisted by industry. Toxic Substances legislation is said to intrude on trade secrets, plant inspections by the government violate employers' constitutional right to conceal unhealthy conditions in the factory, and the implementation of NIOSH's Health Hazard Evaluation program by examining company medical records is said to compromise individual privacy rights.

Each of these practices is needed if research is to be productive and has been allowed under legislation and regulation. They are now under court challenge and legislative counterattack. The principles of research must reflect this concern in order to support the right to do research.

3. Interdisciplinary research efforts must be accorded a higher priority than they currently receive.

The environmental and occupational health field is of necessity multidisciplinary, requiring interaction of clinical medicine, toxicology, engineering, chemistry and epidemiology; many of these fields are themselves multidisciplinary. Because of this there is a continuing weakness with the academic base of the field. Professional status and financial support are much more readily accorded to the so-called pure disciplines, as are programs of educational or professional development. The Environmental Health field is usually shunted into a portion of the School of Public Health, and accorded poor status and funding within a university or medical school. Occupational Health trails behind even in this subdiscipline.

The UAW's judgment is that the change of thinking required to reverse this condition will have to be, at least in part, forced on academic institutions from the outside.

4. It is the social responsibility of scientists to understand the public health regulatory needs, and to take these into account in planning research.

The plan for scientific work in this field must be informed by understanding of the regulatory questions which new knowledge is designed to answer. This requires a familiarity with issues by the scientists as well as a familiarity with the scientific process by the regulatory administrators.

5. Part of the social responsibility of scientists is the obligation of the research establishment to communicate its knowledge to the regulatory agencies and legislative bodies.

The role of scientists who testified in OSHA's carcinogen hearings brings this into focus. One special concern in this regard is the interpretation of negative experimental and epidemiological findings, for example, a negative result in a low dose animal study in the face of a carcinogenic response at a high dose, or a negative finding in an epidemiological study in the face of a positive animal study. Scientists should indicate the chances of false negatives in their communications. Further, where definitive data is lacking, scientists must not simply call on the government to delay action in the face of long delays in completing studies or questions which are scientifically intractable. Finally, where scientists pose a conclusion in layman's terms, such as the assertion that "high doses overcome the body's natural defense mechanisms against cancer-causing chemicals," they must indicate which parts are scientifc concepts, which are metaphors, and which are partially contradicted by experimental findings.

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International Year
of the Child 1979

NATIONAL REYES SYNDROME FOUNDATION

P. O. Box 161 • Dexter, Michigan 48103

HEALTH REGULATION AND PROMOTION

October 1, 1978

My name is James C. Crawford. I am currently serving as a Vice President of the National Reyes Syndrome Foundation of Michigan. I reside in Hingham, Massachusetts with my wife and three children. I appreciate this opportunity to participate in the National Conference on Health Research Principles sponsored by the Department of Health, Education and Welfare.

I will address the problem of Reyes Syndrome particularly with regard to reporting of its incidence and epidemological work.

Reyes Syndrome since its description by Reye et al in New Zealand and Johnson et al in the United States in 1963 has been increasing in incidence and severity. Reyes Syndrome is a disease of the Liver with encephalopahthy of the Brain which afflicts predominately young people. During the period December 15, 1973 through June 30, 1974, three hundred seventy-nine (379) cases of confirmed Reyes Syndrome were reported to the Center for Disease Control. This caused many individuals in the health field to refer this period as of epidemic proportions. Prospective surveillance of Reyes Syndrome in Michigan revealed the occurrence of forty-six (46) cases between December 15, 1973 and June 1, 1974. In an attempt to determine the incidence of Influenza B associated with Reyes Syndrome, a randomized point prevalence survey of 1,041 school children was done in Kalamazoo County where there had been simultaneous outbreaks of Influenza B and Reyes Syndrome. Based upon this County-wide survey, the incidence of Reyes Syndrome following Influenza B was estimated as between 30.8 and 57.8 cases of Reyes Syndrome per 100,000 cases of Influenza B. In fact, the total number of reported cases of Reyes Syndrome in 1974 is more than the total number of reported measles, mumps and vericella encephalitis cases combined (379 versus 241). This data suggests that during Influenza B outbreak the incidence of Reyes Syndrome in effected communities may be expected to be greater than that of most viral associated diseases of the central nervous system.

During the period December 1, 1976 through November 30, 1977, 425 suspect cases of Reyes Syndrome were reported to CDC. Unfortunately, it is most difficult to estimate the actual number of cases of Reyes Syndrome due to incomplete reporting, difficulty in diagnosing milder cases and the probable existence of sub-clinical disease. A recent comparison of cases reported to CDC with cases to this Foundation suggest that the disease may be considerably under-reported.

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The Center for Disease Control has encouraged volunteer reporting from State and Territorial Epidemolgists, hospitals and private physicians throughout the United States. This solicitation has achieved random and limited reporting. This Foundation has pursued as one of its goals to enact mandatory reporting in every State to ascertain the true scope of the Reyes Syndrome problem. Needless to say, enacting State legislation can be a most time consuming effort.

> Consider: In one State, Foundation representatives pursued reporting for six months receiving the support of State House and Senate Health Committees only to have the Governor pocket veto the Bill. Upon continued pursuit for an additional six months, the Bill was signed into law.

At this time, seven (7) states have enacted mandatory reporting requirements for Reyes Syndrome.

In regard to defining the epidemiology of Reyes Syndrome, this is of most essential importance. CDC recently conducted a prospective sixteen (16) months surveillance period extending from December 1976 through April 1978 and on a retrospective population based study in Ohio in the years 1973 - 1977, this study covering temporal distribution, geographic distribution, age distribution, race distribution, social economic status, revealed some different trends from those previously reported. The investigators called for additional epidemiological investigations of defined populations where legitimate attack rates can be obtained will be necessary to determine the true epidemiology of Reyes Syndrome. Additional population based studies are needed to determine if relationships found are typical of the United States.

The Reyes Syndrome problem has shown an occurrence in pocketed areas over a given time period. Numerous occurrences in the same geographic location over an extended time period, the occurrence in siblings and other related family members, reoccurrence in the same victim, et cetera which all call for sound epidemiological studies.

On June 22, 23, 1978, an International Conference on Reyes Syndrome was held at Halifax, Nova Scotia. This Foundation along with the National Institute of Neurological Communicative Disorders and Stroke and other agencies served as co-sponsors to this Conference. A constant theme throughout this affair was to determine the known incidence of Reyes Syndrome and calling for broad epidemiological investigations to determine the ideology of Reyes Syndrome.

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This Foundation would also advocate the following programs being implemented through the Department of Health, Education and Welfare through its Health agencies to combat Reyes Syndrome.

1. An active, continuous surveillance program to determine the incidence of Reyes Syndrome in the United States.
2. Broad epidemiological investigations to determine the ideology of Reyes Syndrome so as to provide information regarding the cause of causes, the pathogenesis, the most effective mode of therapy, and hopefully the prevention of Reyes Syndrom.
3. A disemination of publications on Reyes Syndrome to State and Territorial Epidemolgists, hospitals & private physicians throughout the United States.

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Marjorie C. Becker, Ph.D.
Assistant Dean/Director
Allied Health Education
University of Michigan, Ann Arbor
Panel #3 Health Regulation and Promotion

Ladies and Gentlemen of the Panel on Health Regulation and Promotion, I am Marjorie Becker from the University of Michigan; a Past President of the Allied Health Professions Section of the Arthritis Foundation; and currently a lay member of the National Institute of Arthritis, Metabolism and Digestive Diseases. Beginning as a physical therapist, I have spent my entire professional career in patient care, health manpower training and administration, currently being the Assistant Dean and Director of Allied Health Education at the University of Michigan Medical Center.

I wish to briefly emphasize a few points from the point of view of a very practical administrator who appreciates that our present pool of health resources cannot possibly satisfy growing societal or individual wishes. Therefore, I pose the following principle for this Panel:

> Of the several health research foci under current discussion, research in health regulation and promotion is recognized to be of importance but should be of lowest priority for resource allocation. Within this specific research focus, I would further prioritize research in high incidence disease prevention as requiring greatest attention followed by research in the efficacy of therapy, (control), health education, intra-DHEW communications and regulation, being of lowest priority.

The following suggestions are offered toward implementation of this principle:

Regulatory research should be directed toward de-regulation in the areas of manpower and academic health science institutions in which these professionals are trained and do research. The very life line for producing manpower and scientific endeavor is being strangled by red tape and regulations.

Within the sphere of health manpower regulation, it is contradictory and unproductive to purposely broaden the qualities and charisteristics of the health professions student candidate pool, educate them and then require proof of competency and provision of quality through costly regulations of these health professions and institutions in which they are trained or employed. It would be much less expensive to regulate at the "front end" or through the institutional licensure of health teams since health care is increasingly being provided by groups of health professionals working in an organized framework.

Research on the efficacy of therapy is needed. Such research is actually a cost containment measure. With a systematic approach and a small research investment, the effectiveness of present therapies could be determined as well as their appropriateness for continued reimbursement. This effort may discourage proliferation of health occupations whose treatments are deemed to be of less than acceptable benefit.

Research attention should be directed toward effective teaching of health, health habits and the impact of disease in our primary and secondary schools. Adult health behavior patterns should be influenced through linkage to the reimbursement system which will be less costly and less time consuming in the short run than through behavior modification research.

Incentives should be established to encourage health science centers, voluntary health occupations and the private sector to develop innovative and cooperative methods of public education regarding the application of biomedical research in promoting better health habits.

The present regulatory agencies of DHEW should continue to be considered the "gate keepers" for fundamental research in health regulation, promotion and prevention. At the same time, efficiencies must be encouraged by the systematic interaction among these regulatory agencies and their basic research agency colleagues.

Lastly, the time and effort grant recipients must spend in accountability activities should be reduced. Increased rigor at the point of application may reduce the valuable and potentially productive time lost in the accounting process.

Except as I have otherwise indicated, I support the DHEW and public agencies' statements re: health research principles. They are well stated. Once a research strategy is developed, safeguards should be encouraged to minimize disruptions to it by future political and staffing changes.

Thank you.

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American Osteopathic Association

J.J. Rodos, D.O.
Associate Executive Director
American Osteopathic Association

Panel: Health Regulation and Promotion

Mr. Chairman, I am Doctor Jerry Rodos, Associate Executive Director of the American Osteopathic Association and until June, 1978 a practicing physician in Cranston, Rhode Island. The American Osteopathic Association represents the 16,000 osteopathic physicians of this country, 75 percent of whom are in family practice.

It is from this base that I should like to use these few minutes to emphasize one facet of the many areas which fall into this panel's purview. The key word of this facet is credibility. Other areas of concern have been identified in the September 15, 1978 agenda to this conference and deserve the careful attention that this panel is according them in hearing testimony today and tomorrow. The agenda raises many serious concerns. The response to some of these are not readily at hand and will require ongoing work to develop. But I should like to suggest that credibility be a key underpinning of these concerns. The Secretary raised the need to direct some research efforts into the areas of the Department of Health, Education and Welfare's primary responsibilities and that is reasonable and proper. He also raises the need to direct research or to have research directed into issues of national policy, and this reasonable and proper. But the key to this research again is credibility. The conclusions produced from the data research projects must be creditable in methoding conclusions. This is a basic dictum of all research, it is even more acute in areas of research related to the responsibility of the Department of HEW and resultant public policy. As a practicing physician let me emphasize how critical this is. Decisions on drugs, additives, preventive medicine and illness care should be based on vowed creditable research. I believe we all would agree with that statement. But our track record does not stand up to that statement. Far too often we have removed drugs and food stuffs from use, only to find later that the method was faulty or that the conclusions failed to establish any relationship between a test animal used in the experiment and man. The resulting publicity or reversal in policy produces a significant credibility gap. The practicing physician is thus placed in the position of having to counsel his patient to accept or reject information that is provided over the media sources, and as a practicing physician let me tell you how difficult it is to do this. In my opinion we are fast drawing to a time that the faith that the public will have in science and especially science and government will have reached such a low level that even valuable data produced will fail to change the practice and life style of our citizenry.

I am suggesting that research conclusions before they impact so dramatically on the areas that I have mentioned before be reviewed by an impartial panel of examiners, so that their inherence to valid scientific principles are validated before their impact on policies of the Department of HEW and our government in general are affected.

Thank you for this opportunity.

Richard D. Remington University of Michigan

COMMENTS ON HEW MULTI-YEAR STRATEGY FOR SUPPORT OF HEALTH RESEARCH*

FROM THE ASSOCIATION OF SCHOOLS OF PUBLIC HEALTH

THE ASSOCIATION OF SCHOOLS OF PUBLIC HEALTH REPRESENTS THE TWENTY ACCREDITED SCHOOLS OF PUBLIC HEALTH LOCATED IN SOME OF THE LARGEST AND BEST RESEARCH UNIVERSITIES WITHIN THE UNITED STATES. A NUMBER OF SCHOOLS OF PUBLIC HEALTH OPERATE WITH A RESEARCH BUDGET WHICH IS, ON A PER CAPITA BASIS, LARGER THAN THAT OF ANY OTHER SCHOOL OR COLLEGE WITHIN THEIR RESPECTIVE UNIVERSITIES. THIS RESEARCH RANGES FROM THE BASIC HEALTH SCIENCES OF BIOSTATISTICS, EPIDEMIOLOGY, AND THE BEHAVIORAL SCIENCES TO APPLIED RESEARCH INTO THE ORGANIZATION, DELIVERY, EFFICIENCY AND EFFECTIVENESS OF PERSONAL HEALTH SERVICES AND THE INVESTIGATION OF ENVIRONMENTAL FACTORS IMPACTING ON HUMAN HEALTH. THE SCHOOLS OF PUBLIC HEALTH APPLAUD AND SUPPORT THE ADMINISTRATION'S EFFORT TO DEVELOP A BETTER STRATEGY TO GUIDE THE ALLOCATION OF THE FEDERAL RESEARCH DOLLAR. A STRATEGY FOR HEALTH RESEARCH BASED ON A SYSTEMATIC AND COMPREHENSIVE ASSESSMENT OF RESEARCH AND HEALTH NEEDS IS LONG OVERDUE.

GOVERNMENT SUPPORTED RESEARCH MUST HAVE A STRONG ORIENTATION TOWARD IMPROVING THE QUALITY OF THE NATION'S HEALTH AND THE EFFECTIVENESS OF ITS HEALTH SERVICES, AND MUST BE MORE EFFECTIVELY ORIENTED TOWARD DEVELOPING KNOWLEDGE BASES THAT SUPPORT PREVENTION, DELIVERY, REGULATION, STANDARD SETTING AND COST CONTROL. WE ARE ENCOURAGED BY THE SPOTLIGHT SECRETARY CALIFANO HAS PLACED ON THE SCHOOLS OF PUBLIC HEALTH AND THE PARTNERSHIP ENVISIONED BETWEEN SCHOOLS OF PUBLIC HEALTH AND OTHER RESEARCH INSTITUTIONS. THIS EMPHASIS HIGHLIGHTS THE

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*PREPARED FOR NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES, OCTOBER 3-4, 1978.

NEED FOR INCREASED RESEARCH IN BIOSTATISTICS, EPIDEMIOLOGY, HEALTH BEHAVIOR, HEALTH SERVICES, ENVIRONMENTAL HEALTH AND NUTRITION. DEVELOPMENTS IN THESE AREAS SHOULD BECOME A NATIONAL PRIORITY.

IF SUCH A PRIORITY IS ESTABLISHED, SEVERAL STEPS WILL BE NEEDED TO PROVIDE FOR IT:

1) INSTITUTIONAL AND PROJECT RESEARCH WITHIN THE SCHOOLS OF PUBLIC HEALTH SHOULD BE INCREASED BY LARGER ALLOCATIONS TO THE AREAS OF BIOSTATISTICS, EPIDEMIOLOGY, BEHAVIORAL SCIENCES, HEALTH SERVICES, ENVIRONMENTAL HEALTH AND NUTRITION. THESE ALLOCATIONS SHOULD BE AWARDED, IN KEEPING WITH LONG ESTABLISHED AND PROVEN TRADITION, ON A COMPETITIVE BASIS AND SUBJECTED TO RIGOROUS PEER REVIEW.

2) SUPPORT FOR RESEARCH TRAINING IN THESE AREAS SHOULD BE INCREASED IN ORDER TO GUARANTEE AN UNDIMINISHED FLOW OF YOUNG INVESTIGATORS ENTERING THE POOL OF TRAINED RESEARCH WORKERS. THIS CANNOT BE OVER EMPHASIZED SINCE POLICIES OF RECENT ADMINISTRATIONS HAVE NOT ENCOURAGED THE PREPARATION OF RESEARCH SCIENTISTS IN ANY AREA, CERTAINLY NOT THESE AREAS.

3) DEPARTMENTS OF PREVENTIVE MEDICINE AND COMMUNITY HEALTH WITHIN MEDICAL SCHOOLS SHOULD BE STIMULATED TO GROW AND TO DEEPEN THEIR RESEARCH PROGRAMS IN THESE CRITICAL FIELDS.

BY FEDERAL POLICY, RESEARCH ON THE COST IMPLICATIONS OF PREVENTIVE STRATEGIES SHOULD BE DEVELOPED AND SUPPORTED. ONLY A CLEARLY STATED POLICY AND A WELL-SUPPORTED FEDERAL PROGRAM CAN PROVIDE THE NECESSARY GROWTH SPURT TO ENCOURAGE YOUNG INVESTIGATORS TO ENTER THIS WORK, TO ENCOURAGE WELL-ESTABLISHED INVESTIGATORS TO MOVE INTO THE FIELD, AND TO ELEVATE THIS INVESTIGATIVE AREA TO ITS APPROPRIATE PRIORITY LEVEL.

THE IMPACT OF THE ENVIRONMENT ON HEALTH AND DISEASE AND THE COST OF CORRECTING THE RESULTANT HEALTH PROBLEMS IS ONLY POORLY UNDERSTOOD IN SPITE OF DECADES OF EMPHASIS. NEW RESEARCH METHODOLOGIES MUST BE DEVELOPED, AND IT WILL FALL LARGELY TO THE FIELDS OF BIOSTATISTICS AND EPIDEMIOLOGY TO DEVELOP THESE TECHNIQUES.

AN UNFORTUNATE TENDENCY EXISTS WITHIN THE FEDERAL GOVERNMENT AT PRESENT TO IMPOSE UNREALISTIC CEILINGS ON THE NATION'S HEALTH RESEARCH CAPABILITY. WE ARE CALLING ATTENTION IN THIS STATEMENT TO A LACK OF HISTORICAL EMPHASIS ON SEVERAL CRITICAL FIELDS OF HEALTH RESEARCH. THIS LACK OF EMPHASIS WILL NOT BE CORRECTED THROUGH SIMPLE REALLOCATION OF RESOURCES AWAY FROM OTHER NECESSARY CATEGORIES OF BASIC AND CLINICAL RESEARCH.

ALTHOUGH THE NATION'S HEALTH BUDGET IS IMPRESSIVE, APPROACHING $200 BILLION PER YEAR, ONLY ABOUT 2 PERCENT OF THIS BUDGET IS PRESENTLY DEVOTED TO HEALTH RELATED RESEARCH IN ALL CATEGORIES. IN THE PRIVATE SECTOR, NO RESPONSIBLE MANAGER SEEKING COMPETITIVE ADVANTAGE THROUGH THE DEVELOPMENT OF NEW

TECHNOLOGY WOULD INVEST SUCH A SMALL PERCENTAGE OF TOTAL BUDGET IN THE RESEARCH AND DEVELOPMENT AREA. AT LEAST NOT WITHIN AN INDUSTRY CHARACTERIZED BY COMPETITION. THE HEALTH INDUSTRY FINDS ITSELF IN COMPETITION WITH INCREASINGLY STUBBORN AND RECALCITRANT DISEASE PROBLEMS. THESE PROBLEMS WILL REQUIRE THE DEVELOPMENT OF NEW METHODOLOGY APPLIED IN NEW WAYS. A DECISION THAT NO NEW FUNDS SHOULD BE ALLOCATED TO THESE DEVELOPMENTS IS POOR PUBLIC POLICY.

AS A NATIONAL PRIORITY, THIS NATION'S POLICYMAKERS MUST DECIDE THAT THE HEALTH SECTOR REQUIRES IMPROVED FUNDING OF BASIC AND APPLIED RESEARCH WITH PARTICULAR EMPHASIS ON THE CRITICAL AREAS OF BIOSTATISTICS, EPIDEMIOLOGY, BEHAVIORAL SCIENCES, HEALTH SERVICES, ENVIRONMENTAL HEALTH AND NUTRITION, SINCE TOTAL FEDERAL RESOURCES ARE LIMITED, THESE ALLOCATIONS MUST NECESSARILY BE TAKEN FROM OTHER, NON-HEALTH RELATED AREAS OF THE FEDERAL BUDGET. YET, IN TOTAL DOLLAR MAGNITUDE, THE SUMS OF MONEY INVOLVED ARE NOT LARGE, PARTICULARLY IN COMPARISON WITH BUDGETS OF SEVERAL OTHER FEDERAL FUNDING SECTORS. THE NATION'S SCHOOLS OF PUBLIC HEALTH STAND READY TO ASSIST THE FEDERAL GOVERNMENT IN ITS PLANNING AND ALLOCATION EFFORT IN THESE IMPORTANT AREAS.

Testimony of Alan J. Douma, M. D.

The George Washington University

It is very pleasing to find that the draft of the Department of Health Education and Welfare Health Research Principles suggests a significant increased emphasis on the preventive approach to good health. This is particularly true regarding the recognition that prevention is and should be woven into the entire health delivery framework. In general, I agree with the statements made about the role of importance of prevention mechanisms in the report. However, there are two major flaws in the draft report which I will address first.

Combining health regulatory and promotional activities in the same category is very unfortunate. This is inappropriate from an operational point of view since there is very little congruence in theoretical content, application or personnel, between these two very distinct areas. More importantly, the ensuing controversy and fighting over the role of regulation will have significant and unnecessary negative impact on enhancing health through health promotional activities.

The second major flaw concerns money. Throughout the document appears the recognition of the need to change the allocation of resources to obtain a more productive balance between disease prevention and treatment. I could not agree more. However, it is also repeatedly stated that monies should not be taken from any existing programs. These two sets of statements are not compatible given the economic and political circumstances within which this agency and government exist.

It is never easy to decrease funding for a laudable project even when that is the only way to pursue a more productive pathway. If decisions being made at this time were easy, there would be no need for all of us to be here. We now need to commit ourselves in advance to face difficult decisions and make choices. What will be chosen will depend on multidisciplinary interaction and compromise.

As with any attempt to change, the governing factors are; attitude and motivation. This is equally true for health professionals and consumers, particularly because of the strong influence each has on the other's attitudes.

Many of our previous educational efforts have been frustrating with respect to changing practice patterns and lifestyles. In large measure this is because we all live in a society of excessive dependence on the health professionals. This "Marcus Welby" attitude is demanded out of fear and ignorance by the consumer and fostered by the professional. This needs to be recognized and dealt with in every health promotional effort.

Adequate testing of hypotheses and strategies may require changing this attitudinal milieu for an entire community through simultaneous intervention at multiple levels. This would require commitment to an effort of far greater magnitude than has been done to date.

There are 3 main facets in the effort to take full advantage of any emerging technology.

1) Collection and analysis of existing experience and knowledge

2) Use of these results by specialists to design and test hypotheses.

3) Application of validated hypotheses through dissemination to the professional and the consumer.

I will briefly discuss specific areas of research and development which address each of these facets.

There is an immediate need for full funding and development of the clearinghouse concept, utilizing available expertise from many specialty areas. This effort would begin by collecting a complete set of print and audio-visual materials. It is important that this not merely become a repository of information. Its major effort should be directed toward synthesis and dissemination in a form most appropriate to the receiver. This activity would be enhanced by development of regional centers with their major activity being encouragement of the use of the clearinghouse.

Greater numbers of specialists are needed to carry out projected research requirements. However, the imbalance of prevention and treatment is nowhere more dramatic than in training. This is exaggerated by the long lag time between changing of philosophy and production of specialists. DHEW should sponsor studies to determine the most expeditious means to increase the number of such specialists including mechanisms by which practitioners may become trained without complete disruption of their present practice.

At the core of the problem is; how do we impact on the consumer? There are two areas which are beginning to be looked at and we need to strongly encourage their further research and development. These are television and the workplace.

We are all aware of the vast amount of time people spend watching television. As health professionals, we need to learn how to use television as the potential tool that it is. This is to include its effects on our role models and expectations as well as its contentual educational role.

The workplace provides a unique arena for impacting on large numbers of people. I recommend that DHEW encourage and join with business and labor in their rapidly growing concern and efforts toward health promotion. Support needs to be given to rigorous testing through prospective pilot studies and retrospective analysis of ongoing programs of health promotion for the worker.

Testimony Presented to the Panel
on Health Regulation and Promotion
Inez Hinsvark, Project Director
Credentialing in Nursing
American Nurses Association

National Conference on Health
Research Principles

October 3, 1978

I want to thank you very much for letting me speak on this very impromptu basis. My concern is with the lack of emphasis on research, and thus, of the budget for research on the regulation of health manpower.

Regulation of health manpower is fundamental to the health and safety of the public. Today there is a multi-sided tug-of-war among the professional associations, academe, consumer groups, state governments, and the departments, agencies, and bureaus of the federal government, over who should have ultimate control over the health care sector. The recent entry of the Federal Trade Commission onto the battleground, on the basis of restriction of trade and monopolistic practices, is a good example of the growing trend for federal regulation over that sector.

On the other hand, the total control of an occupation or profession over its area of practice can lead to a spiraling effect of ever higher standards and ever high costs. Restraints and stresses placed on services due to this can deprive the public of safe health care. The entire problem of regulating health manpower needs much more attention. The studies heretofore have been within the structure of government or within a specific professional field, and both of these are a very limited basis for studies.

During the past year I have been involved in an intensive study of credentialing, funded by the American Nurses Association. The current pattern of credentialing indicates chaos in all arenas of credentialing, not only in nursing, but also in other health and related professions as well.

Our goal of creating a new or revised system of credentialing for nurses is hampered by a lack of valid and reliable information on: costs of credentialing; clear delineation of the turf of each health professional group; relationship of credentialing to quality health care; unclear base within the professions, particularly where the levels of that type exist (thus the positions here); no clear demarcation between the states' rights and the federal laws in the control of practice; the government vs. the professions' rights to set standards; and the like. These are all problems that need research. Nowhere in the health research principles, which will be used as a guide for development of the five year plan for health research, do I find attention being paid to these problems and other related issues. Therefore, I recommend that a substantial and adequate amount of the research budget be allocated to the study of credentialing of health manpower and its related activities.

STATEMENT BEFORE PANEL ON HEALTH REGULATION AND PROMOTION AT THE NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES, OCTOBER 3-4, 1978.

by
Sorell L. Schwartz, Ph.D.
Professor of Pharmacology
Georgetown University, Schools of Medicine and Dentistry
Washington, D.C.

Representing Public Affairs Committee of Federation of American Societies for Experimental Biology

Legislation intended to establish standards for the environment, the work place, food, drugs has all been aimed at the protection of human health and has resulted from the demands of the public to ensure its safety. This has, in turn, created a regulatory environment which necessitates the gathering and processing of substantial amounts of scientific data. There is a high liklihood, however, that we run the danger of making regulatory decisions based on what Burger has termed "unmature science"[1]. He stated: "In our zeal to regulate we have permitted many well intentioned government decisions to be made with information . . . based on scientific investigation . . . which is frequently reflective of what most traditional scientists would consider a thin fabric of science . . . . It has not been uncommon for the results of pilot or preliminary experiments to be taken directly into government decision action without the benefit of confirmation and interpretation . . . to establish proof and confidence."

Part of the use of unmature data results from the pressures on and by non-scientists; some of it results from design and/or interpretation of experiments by incompetent scientists; and some of it is a reflection of the zeal of good scientists, who should know better, but are enamored of the influence their work and decisions have on the regulatory process. Last summer, for example, OSHA held public hearings on its proposed emergency standard for benzene in the work environment. Though it is fairly well agreed upon that benzene is a leukemogen, there was a question whether it was a leukemogen at concentrations of 10 ppm. OSHA based its decision to lower the allowable exposure, in part, on a NIOSH epidemeological study which created a significant degree of controversy. A panel comprised of NIOSH and NCI scientists was present to answer scientific questions.

It was bought out by an attorney representing the petroleum industry that he had learned through documents obtained under the Freedom of Information Act that a noted NIOSH toxicologist condemned the epidemeological study. This caused one of the NIOSH scientists present to make an unflattering remark, for the public record, about the toxicologist. An NCI toxicologist who was also on the panel told me later that day that he was infuriated with the remark and would no longer defend the NIOSH study. This particular incident comprises a number of factors but the main one is whether the pressures of the regulatory environment are going to lead to a compromise of standards in the scientific decision making process.

Both the scientific and lay public have a right to expect high quality professional science in its regulatory decisions. I submit, that those at the decision making levels do not necessarily have the in-house resources at hand to meet that expectation. However, to some degree, resources are at hand in the non-Federal scientific community. The peer review system for the purpose of advising on decisions by granting agencies is, with only a few dissenters, agreed to be not only fair and effective, but, economically, one of the few bargains in the Federal bureaucracy. There appears to be a reluctance on the part of regualatory agencies to share "authority" with scientific advisory committees. Where this has been done, success has exceeded failure. There are many scientists in academia and industry who are willing to participate within the government decision making process. Perhaps if such a system was more widespread, a mutual benefit would result which would do much to reduce cynicism and exasperation on the part of regulators and the regulated alike.

I will conclude with another citation from the paper by Burger[1]: "It can be assumed that political incentives will continue to favor the rushing of unmatured scientific observations into regulatory action usually in the name of human health. What is needed, therefore, is a device for foreshortening but preserving the traditional process of maturation . . . . whatever process is eventually chosen, it must be sufficiently visible and available to the public to remain credible and accountable."

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[1] Burger, E.J., Jr., J. Toxicol. Environ. Health, 2:389, 1976.

GEORGE J. THEOBALD, JR. THE NATIONAL HEMOPHILIA FOUNDATION

The National Hemophilia Foundation is most pleased to be invited to participate in this National Conference on Health Research Planning Principles and applauds the Secretary of Health, Education and Welfare, Joseph A. Califano, Jr., for his perspicacity in convening such a distinguished group so that their thoughts on the directions and emphasis of research initiatives may be brought to the attention of the government and to the National Institutes of Health.

The government, its agencies, and the Institute, must become more responsive to the needs and desires of the private sector. The taxpayer is properly demanding more and more accountability, not only from its representatives in Congress, but also from governmental agencies. Misconceptions on research goals abound, and many worthwhile projects, some of which are undeniabley esoteric, have been ridiculed in the popular press. Is it any wonder then, the people ask "Is this the way my tax dollars are spent?".

Proper communications are one of the essential elements, and communications are a two-way street. But, they should not remain exclusively within the confines of the scientific community. The private sector, John Q. Public, is eager to learn what scientific initiatives are being undertaken, the rationale for the projects, an honest evaluation of expectations --- in other words, the translation of scientific progress into terms that are meaningful to the layman. In this way, positive support can be engendered.

Therefore, the Foundation urges that liasion between the Federal Government agencies and voluntary health organizations be encouraged and increased. Joint support of conference research projects are just one example and would certainly be cost effective.

It is further recommended that the Department (DHEW) and the Institute (NIH) utilize the voluntary health agency public relations forum which could become an important factor in creating a direct line to their own constituencies and to the general public regarding the translation of basic research data.

The Foundation is concerned that ever-increasing clincial trials require additional dollars, and it appears that entire budgetary allowances could be expended in this field alone.

Therefore, the Foundation proposes that the Institute explore, create and expand formalized relationshps with industry to help support this type of research. There is already precedence within NIH for this, and in addition the Persantine Aspirin Reinfarction Study (PARIS) is one example of industry supporting significant, unbiased clinical trials. It is our opinion that this type of collaborative funding should be sought by the Institute, and by other governmental agencies as well, so that important clinical trials can be expanded with modest impact upon already stringent budgets.

As a national voluntary health organization, we also are concerned with costs and carefully review our own programs to eliminate possible duplication of efforts. This also should be an objective of the Institute.

The Foundation recommends the development of effective inter-institute and inter-agency groups to deal with an overall review and analysis of all programs to insure elimination of non-essential duplication of efforts.

A committee similar to the one currently existing at the National Heart, Lung and Blood Institute (NHLBI) could well serve as a model for this program. Such a group must insure non-duplication of efforts among the Institutes and in our opinion, it should be a small, active group having decision making power with direct input into the budgetary process.

Finally, the Foundation suggests that a similar mechanism be devised to permit the institutes and agencies to report to appropriate congressional committees regading recommendations, and progress of programs to insure their support and financial commitment of the Congress.

The National Hemophilia Foundation is appreciative of being permitted to present its views at this conference.

GEORGE J. THEOBALD, JR. THE AMERICAN BLOOD COMMISSION

The American Blood Commission is a nonprofit organization working to build a national blood program which will insure an adequate supply of safe voluntarily donated blood to meet the needs of all the people in the United States.

Because of the wide variety of needs and uses for blood and blood products, the interest of the Commission represents the research interests and clinical requirements of many organizations and thousands of scientists, as well as those of millions of Americans who at one time in their lives will need this essential natural resource.

The Commission was established just over three years ago. It now consists of forty-three national organizations, associations and societies that believe that an efficient and effective national blood system in this country can be strengthened and sustained by the private sector. However, a very special relationship exists between this private sector effort and The Department of Health Education and Welfare and especially with The National Institutes of Health.

This relationship derives from the fact that the Department of Health, Education & Welfare articulated the national blood policy in 1973. The policy is a statement of goals for the United States and for all patients that require blood which is being implemented by The American Blood Commission.

The research and development projects, feasibility and planning studies, demonstration programs, and other activities of The American Blood Commission - which are all designed to attain the goals of the National Blood Policy and to build a responsive and responsible blood program for the people of the United

States - represents applied research in a most fundamental sense. For it involves the application of research as well as policy planning in a system-wide effort to improve the provision of service thoughout the country.

We recognize the fine line that can be drawn between basic and applied research. The fourth principle emancipated by Secretary Califano in his speech before the American Federation for Clinical Research, namely, "our government supported research must have a strong orientation toward improving the quality of our Nation's health and effectiveness of this Nation's health services", is particulary related to the work of the American Blood Commission, for the Commission is directly involved in such research which pertains to the management of the National Blood Resource. We believe that such applied research is important in fundamental research and that both kinds of endeavors must be equally considered in working towards the goal of providing quality health service.

In order to develop a successful combined formula of basic and applied research, I hope that particular attention will be given to strenghtening communications and coordination among health agencies. This is extremely important if we are to work cooperatively toward a common goal. In addition, it is important to recognize that the mission of health research consistently must be brought to the attention of the public.

Because of the essential importance of blood and blood services to the American people and because of the historical interest as well as the mandate of the National Heart, Lung and Blood Institute, which now focuses on the effective management of the national blood resources, the American Blood Commission submits these recommendations and looks forward to doing its part together with other major health agencies in making the health principle goals a reality.

AMERICAN PSYCHOLOGICAL ASSOCIATION
1200 SEVENTEENTH STREET, N.W.
WASHINGTON, D.C. 20036

Telephone: (Area Code 202) – 833-7600

October 16, 1978

Mr. Kurt Habel
Chief, Program Planning Branch
D.P.A., O.P.P.E.
Office of the Director
National Institutes of Health
Building 1, Room 205
Bethesda, Md. 20014

Dear Mr. Habel:

Dr. Lee Sechrest, Professor of Psychology at Florida State University, and a member of the American Psychological Association, has submitted the enclosed comments relevant to the issues considered by the Panel on Health Regulation and Promotion of the DHEW National Conference on Health Research Principles.

We wish to provide this material for the record and hope that it will receive consideration.

Sincerely,

Joan Zaro

Joan Zaro, Ph.D.
Administrative Officer
Office of Professional Affairs

JZ/ljm
cc: Dr. C. Kiesler
Dr. L. Sechrest

Department of Psychology
The Florida State University
Tallahassee, Florida 32306

October 4, 1978

Dr. Joan Zaro
American Psychological Association
1200 Seventeenth Street, N.W.
Washington, D.C. 20036

Dear Joan:

A prevelant view of both health and disease over the past couple of centuries has been that health is the reciprocal of disease and that disease is a result of a malignant process operating on a passive organism. A more recent and more useful view is that both health and disease are the products or outcomes of sequences of behavior by organisms that are anything but passive. We need a better understanding of the behaviors which are the precursors of health and illness and of ways of altering those behaviors. Since psychology is the central discipline in the study of behavior, it should logically have a central role in research into problems of health and disease.

A second aspect of the current view of health and disease is that health is not merely the absence of disease. Rather health can be viewed as a more positive state that is qualitatively, as well as quantitatively different from merely not being ill or suffering from disease. However, we do not as yet know what the consequences, behavioral or otherwise, of the positive state of health might be, and we do not know what the behaviors are that are likely to promote positive health.

For most of human history, medicine has focused on the elimination of disease as a way of promoting health. More recently there has been a growing interest in health as a positive state and a congruent interest in promoting quality as well as, and perhaps in some instances even instead of, quantity of life. We need a better understanding of the views of the wide variety of persons about what constitutes quality of life and also about the trade-offs that may exist between measures taken to promote quantity and quality of life. These, it seems to me, are essentially psychological problems rather than medical problems or sociological problems, but research to date has been quite limited.

In the course of promoting positive health and quality of life our society is going to have to give greater attention to priorities for health interventions and expenditures of health dollars. At present, there are no priority setting mechanisms and priorities are set haphazardly or by developments in technology. Good instances are provided by the truly formidable sums of money which are spent to prevent death of prematurely born infants or of the elderly. When compared to the much lower expenditures which may be permitted in order to promote quality of life, such as in those suffering from long-term chronic disease, psychologists should have an important role to play in helping to assess people's understandings of priorities and the conditions under which they are willing to have priorities altered. Again, however, the research required to proceed has not yet been done.

Psychologists might even contribute in important ways to the current emphasis on cost containment of our health care system. One possibility for promoting cost containment might be to promote new arrangements for health insurance and payment of medical charges. One possibility, for example, might be to develop different health benefit packages from which people could choose and which would result in their being assigned to different risk cohorts for the purposes of paying for and receiving benefits. Psychologists might be very useful in studying the acceptability of alternative arrangements for health insurance and reimbursement systems. These monetary matters are, it seems to me, much too important to be left to the economists.

In any considerations of improving care of illness in this nation far greater attention must be given to problems of management of long term chronic disease. Many of the problems having to do with inadequacy of and delivery of health services stem from problems of long term chronic disease rather than from acute disease. Chronic disease is likely to involve issues of management rather than treatment as more narrowly defined. The medical care system to date has been fairly cavalier in its attitudes about disease management. The prevalent attitude seems to have been that physicians make diagnoses and prescribe medications or other treatments, after which the responsibility becomes that of the patient. Problems of exercise regimens, control of smoking, obesity, adaptation to long term medication problems, and side-effects, etc., are all issues for which psychologists are quite well qualified to make important research contributions.

Psychologists also can contribute in important ways to improving the delivery of health services. Some of these improvements may come about through better selection and training of health service professionals. Others may come about from improving the efficiency or susceptibility of different methods of health service delivery. Still other benefits may be achieved by helping to shift the locus of responsiblity for health service delivery from highly trained professionals to persons at low levels of training, perhaps even in many instances to the persons who need the services themselves.

Overall, one of the greatest needs for improvement in our conception of health is the development of a systems approach to that area. It simply does not do to consider the various aspects of the whole field of health as separate processes, forces, or entities. Rather, they must be seen as parts of an intricate and complex system. Henceforth, work in the area of promoting health and alleviating disease should begin with very explicit recognition of the system into which the results of the research will be incorporated. Research should not be done on isolated aspects of the health care system, but rather should be undertaken with full and explicit recognition of the operations of the system and the way in which the research findings will be incorporated. For example, work on any new technology in health care should be undertaken in light of full understanding of its costs, the persons who would be effected by it, the efficiency and effectiveness with which the technology could be put into service, and the implications for other parts of the system of implementing the technology to be developed in the research project. Moreover, there is no justification for segmenting the health care system into such arbitrarily defined parts as physical health, mental health, dental health, and the like. There is more and more reason to believe that various aspects of health cannot be adequately dealt with in small pieces. More effort needs to be devoted to research on understanding of the total health system.

I would like to add an additional comment about the review process for health research. At present, most of the national institutes of health are oriented very narrowly toward biological, biochemical, and medical research. The mission of each of these institutes needs very badly to be rethought. Representation on review bodies needs also to be broadened. Research on behavioral aspects of health care will never be fairly considered as long as review bodies are made primarily of persons with backgrounds in fields such as biochemistry, pharmacology, and surgical technology.

I thought you might be interested in these thoughts of mine. Feel free to use them in any way you think justified. If you should have any questions or comments, by all means let me hear from you.

Sincerely,

Lee

Lee Sechrest
Professor of Psychology

LS:se

Chronobiology and Its Relation to Developing a Knowledge Base for Regulatory Decisions in Health and Prevention

Chronobiology is an emerging science which touches all areas of biological science and is of paramount importance whether we consider fundamental research, clinical application, health services research, or health regulation and prevention, all of which are topics of this conference. I have been asked by my colleagues to discuss the potential of chronobiology to health regulation and prevention. In the instructions sent me, it was stated that one objective of this particular aspect of the conference was to focus on further development of the knowledge base necessary for regulatory decisions and preventive control measures.

To begin with one must briefly explain what chronobiology encompasses. In 1978, it has been documented beyond question that all biological systems change rhythmically along the time course of seconds, minutes, days, months and years. Thus from such data, oscillation has become documented as a fundamental property of life. Such a multiplicity of oscillating frequencies may at first seem awesome and difficult to control or manipulate; thus the tendency has been to ignore them when carrying out basic health-related research, when gathering data to serve as a reference base, or when developing methods for the early detection of disease.

We believe that such an approach is wrong and even dangerous. First let us discuss chronobiology from the viewpoint of obtaining biological information to serve as a data base upon which regulatory decisions are to be made. It must be recognized at the outset that a critical mass of data does exist in the literature documenting the fact that virtually every physiological variable amenable to measurement will fluctuate along the 24-hour time scale. Some have rationalized that the variation we speak of represents no more than minor fluctuations around a daily mean, and consequently does not warrant the additional work or expense required to explore properly for its significance.[1]

Those who believe this simply are ignoring the scientific facts available to them. Admittedly oral or rectal temperature may change only one or two degrees over the 24-hour time scale, but there are few physiologists who would disregard the effect that this small-amplitude rhythm has on metabolic or physiological activity. On the other hand, the cortisol concentration in the plasma of man or of the rodent may vary three- or four-fold along the same time scale, and the same applies to many enzymes in the liver, plasma, brain and other tissues. When 5-hydroxytryptamine levels in the whole brain are measured at frequent invervals over a 24-hour period in rodents, the difference between the lowest and highest recorded means may represent only an 18% change; but the same substance in the pineal gland may vary as much as 900%. When similarly compared, the cell-division rate in a number of tissues, such as the cornea, esophagus and other regions of the gut, may represent a greater than 1200% increase over the daily low. Figure 1 demonstrates such variation in DNA synthesis in the esophagus and tongue of the mouse.[2] Generally, fluctuations in different variables of man when adequately measured are found to be equally as overt as in the rodent.[3]

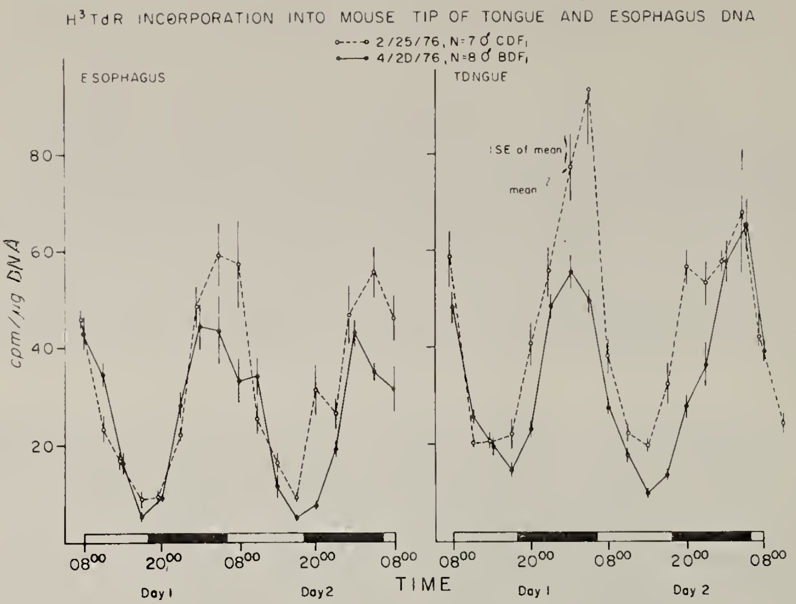

Figure 1. High-amplitude rhythms in the tongue and esophagus in two species of mice.

Accepting the above facts based upon the abundance of data available, the question might be asked: Of what significance is all this? Because the biological system is rhythmically changing over the course of a 24-hour day, the organism is a different biochemical entity at different time points (or circadian stages) during the day. Consequently it reacts differently when identical stimuli are applied at different times. This differential in response to a stimulus according to the circadian stage at which it is applied has been confirmed repeatedly for a variety of stimuli; these include drugs, poisons, chemical substances, physical agents such as noise and X-irradiation, biological agents and endotoxins.[4-6] Moreover, the circadian variation in response to various stimuli may be dramatic.

For example, the duration of sleep resulting from pentobarbital sodium averaged 104 minutes when the drug was administered at one phase of the rat circadian system; but when identical doses were administered at another phase the sleep duration averaged only 43 minutes.[7] When amphetamine was given at one circadian stage, 77.6% of the animals survived; when an equal dose was given at another stage only 6.6% survived (Fig. 2).[8] When a fixed dose of cytosine arabinoside was administered to mice at different circadian stages, 72% of the animals treated at certain times died from drug toxicity whereas as few as 15% died at other times.[9]. Halberg and associates in 1960 injected dimethylbenzanthracene into the salivary glands of mice and found that the incidence of tumor formation occurring weeks later was circadian-stage dependent, with the highest incidence occurring when the dimethylbenzanthracene was injected during the light span. Later, in 1964, these

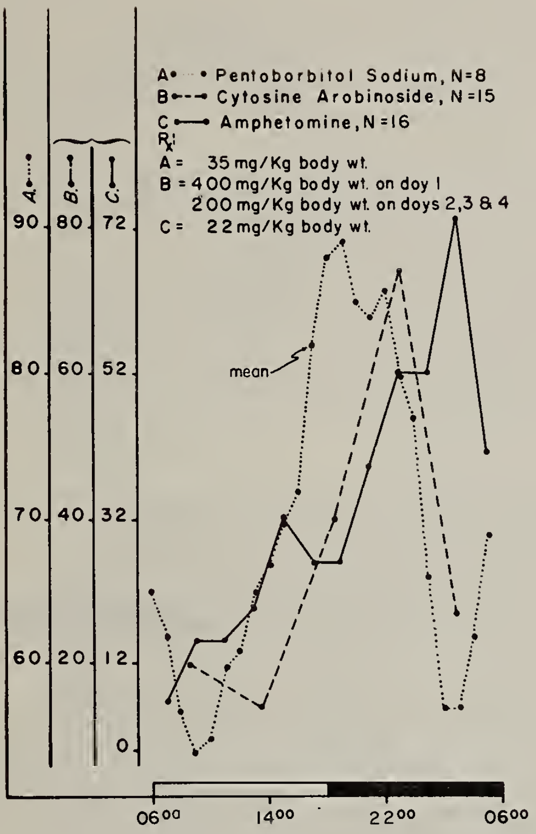

Figure 2. Rhythmic responses in mice to different drugs.

investigators force-fed this same carcinogen to six different groups of fasting mice at different time points (at 4-hour intervals) over a single 24-hour span; they found the incidence of cancer developing in these mice was dramatically circadian-phase dependent.[10] Many well-known carcinostatic drugs, such as the above-mentioned cytosine arabinoside (ara-C), are far more toxic at one phase of the mouse circadian stage that at others.

At present a large amount of experimental data suggests that conventional chemotherapy of cancer can be optimized by timing the administration of drugs according to body rhythms. Optimization has in fact been realized in the rodent by quantifying and exploring rhythms (1) in host susceptibility to the drugs themselves, as well as in the underlying mechanism, e.g., cell division in the bone marrow, gut, thymus and spleen; and (2) in tumor susceptibility gauged directly by tumor size, mitotic activity and DNA formation and indirectly by rhythms in tumor temperature or in excretory products such as polyamines, certain amino acids and light chains, as in the case of immunocytoma.[11-19]

The advantages gained by timed treatment as compared with the best conventional treatment schedules can be dramatic. For example, in one study the combination of cytosine arabinoside (ara-C) and cyclophosphamide was administered to mice beginning 44 hours after injection with 1.2 x 10^6 L1210 mouse leukemia cells.[13] By appropriate timing of the drugs to body rhythms, no deaths from drug toxicity were encountered during the course of treatment; however, when using the conventional treatment approach, as many as 30% of the animals died from drug toxicity. The chronobiological strategy involved treating comparable subgroups of mice at different circadian stages along the 24-hour time scale. The resulting cures were as high as 94% in the animals treated at one circadian stage and as low as 44% at another stage (those animals dying do so from leukemia). A chronobiological approach permitted us to reduce the mortality from the 30% obtained using the conventional treatment approach to zero (Fig. 3).

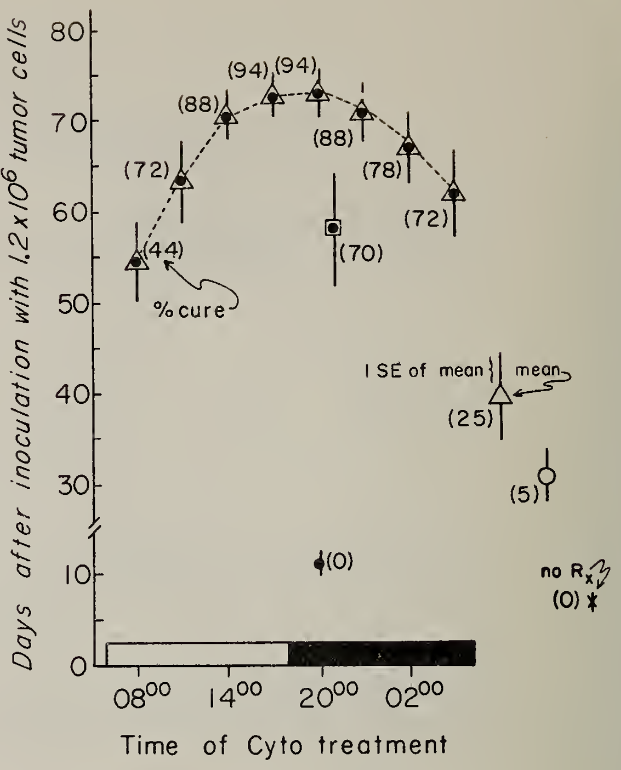

Figure 3. Cure rate in leukemic mice treated with cytosine arabinoside (ara-C) and cyclophosphamide.[18] The △ indicates that at 3-hour intervals each mouse received ara-C in a dose level which varied sinusoidally, with the highest levels given when the host was known to be most resistant to ara-C. Four courses were given with a 4-day rest interval between courses. Each of the 8 subgroups on this sinusoidal ara-C schedule also received once/course a fixed dose of cyclophosphamide, ▲. Another group, □, received the same amount of ara-C but on a conventional schedule of equal fixed doses at each time point; this group also received cyclophosphamide once/course, ⊡. Two other groups received only a single drug, either ara-C, △, or cyclophosphamide, O. Note that 30% of the mice on the conventional schedule died from drug toxicity; none of those on the chronobiological (sinusoidal) schedule did so; if they died it was from leukemia.[18]

Considerable evidence does exist, in addition to the above, to indicate that by timing drugs properly, one can significantly reduce the over-all toxicity and administer more of the anti-tumor drugs without killing the animals. Thus careful consideration of rhythms can optimize the cure rate of cancer.

In May of this year (1978), the International Union Against Cancer supported a workshop entitled "Chronobiology - A Critical Evaluation". The participants in this workshop included internationally distinguished cell kineticists, experimental chemotherapists, immunologists and radiologists, as well as chronobiologists. The objective of the meeting was to determine whether or not these rhythms we have been discussing are of importance to the cancer problem.

At the end of the 2-day conference, it was the consensus of these leading experts that certain guidelines are essential in order to avoid pitfalls that can result from failure to consider chronobiological principles. For example, they felt strongly that it no longer appears to be appropriate to conduct toxicity studies or experimental chemotherapy without consideration of chronobiological principles. They felt that the results obtained without regard to the time factor may be grossly inaccurate and even misleading. It was the unanimous decision of the participants of the workshop to propose minimum standards for animal experimentation in the field of drug testing in general, and in experimental chemotherapy particularly, and to propose these minimal standards to the Food and Drug Administration for inclusion in their "Guidelines for Good Laboratory Practice in Nonclinical Laboratory Studies". Specifically the proposal considered the following points:

"A. Experimental animals to be used in drug testing should be standardized for at least one week prior to study on a regimen of artificial light, with either 12 hours light alternating with 12 hours of darkness (LD12:12), or by choice of the investigator in nocturnal rodents, 8 hours of light alternating with 16 hours of darkness (LD8:16). The latter schedule is found to more closely resemble in the nocturnal rodent the human sleep/wakefulness or activity/rest situation. In diurnally-active animals this schedule could be inverted to 16 hours of light alternating with 8 hours of darkness.

"The lighting regimen chosen should be indicated in any study report on drug testing and/or experimental chemotherapy. It has to be realized that LD12:12 and LD16:8, etc., regimens do not necessarily give identical results. It may be premature at this time to recommend one of the schedules above the other.

"Experimentation done at a given time should be defined by its relation to the light/dark cycle (e.g., LD12:12 with L 06^{00} to 18^{00}, injection time 08^{00}).

"Conditions potentially disrupting to chronobiologic experimentation, such as extreme temperature variations, noise and other disturbance in the experimental room, any unnecessary interference with the animals prior to and during the study, should be avoided.

"B. Since certain periodic phenomena, including sensitivity-resistance cycles, may be phase-shifted by timed food intake, the feeding schedule of the animals should be reported in each study on drug testing or experimental chemotherapy (e.g., ad libitum, starvation, water deprivation, restricted feeding, with time spans given in duration and relation to light-dark regimen).

"C. Due to the sometimes major differences seen as function of circadian system stage of testing, it is recommended that studies of drug toxicity and/or experimental chemotherapy be performed at several time points throughout the 24-hour span whenever feasible. This can be accomplished by injection in synchronized groups of animals at several circadian system phases at different clock hours. Alternatively, the circadian system stage of the experimental animals can be phase-shifted to a time convenient for the investigator by keeping the animals for 1 to 3 weeks prior to study (depending upon the parameter to be studied) in rooms with phase-shifted lighting regimens, or in isolation chambers as described by Dr. Scheving.

"If the times of high and low (acrophase and bathyphase) of a given sensitivity-resistance cycle are established, testing at one or the

> other of these defined circadian system phases may be adequate, provided this is clearly indicated in the description of the study, and any numerical value derived from this study (like LD10 or LD50) is qualified accordingly."

It was also the consensus of the workshop that the experimental results suggest that significant benefits could be derived from the application of chronobiological principles, methodology and treatment schedules to cancer, providing the complex of methodological and logistical problems can be solved. Moreover, there is evidence that the same application can be gained in other areas of clinical medicine.

Consideration of temporal structure may play a role in detection and prevention of certain diseases. Since rhythmic variations in physiological and psychological functioning are fundamental to human life, they offer the key to new insights into the physical, emotional and social life of the individual. There is evidence that rhythms are altered in illness; and the important question of whether rhythm measurement can quantify health can now be tested.

Many studies have demonstrated that individuals can be taught to measure accurately certain body rhythms characterizing vital signs, physiological and physical performance, and the ability to perform mental tasks. As early as 1950, Professor Franz Halberg of the University of Minnesota School of Medicine developed a concept which he referred to as autorhythmometry (self-measurement of body rhythms). He introduced this, on a limited scale, into certain Minnesota high schools in the late sixties. These pioneering studies showed that the high-school student could indeed comprehend and accurately measure a host of rhythms.[20,21] Among the variables measured were: (1) oral temperature; (2) pulse rate; (3) arterial blood pressure (systolic and diastolic); (4) pulmonary function, using a peak flow meter; (5) eye-hand coordination, using a simple apparatus; (6) physical strength, using a grip-strength meter; and (7) mental ability, using several performance tasks. The same studies demonstrated that these students could collect their own urine at periodic intervals around the clock so that the many rhythmic constituents of urine could be measured biochemically. From such studies, which were rigidly quantified, as well as from a host of others on different populations,[3,20-23] many interesting facts have emerged:

1. Physiological, biochemical and psychological variables may undergo dramatic and predictable changes along a 24-hour time scale and such changes can be readily analyzed by modern computer methods.

2. Any average person can be taught, under proper direction by someone knowledgeable in health and in chronobiological principles (in the high school it may be the biology teacher or health educator), to accurately measure variables indicative of body health. The student can carry out such studies in school or at home - all he needs is the proper equipment.

3. Learning about the variations in body function and what their implications are for health makes for better understanding of why, for example, from one time to another a person may feel quite

differently. It may even give one insight into how to deal better with the vicissitudes experienced in everyday living. It is astonishing to me to see the enthusiasm generated in different individuals when engaged in carrying out such studies. In the case of the high-school student, he finds himself using his own body as the investigated subject, which to him is far more appealing than the dissection of the conventional frog (we do not suggest, however, abandoning the frog dissection).

4. For health, the spin-off of such studies is that frequently one finds evidence of rhythm alteration which may indeed be the first indication of disease. Two examples serve to illustrate this. First, arterial systolic and diastolic blood pressure, when measured along the 24-hour time scale, may in some individuals demonstrate a very high-amplitude rhythm, with the peak of the rhythmic variation being within or near the hypertensive range while a majority of the other recorded values may fall within the normotensive range.[3] This raises the question of whether the individual with the higher values found at the peak time will be likely to be a full-scale hypertensive in the future or whether this represents his or her normal pattern? The second example is that of intraocular pressure. As with blood pressure, the rhythm in intraocular pressure when measured along the 24-hour time scale may peak outside the usual reference limits and hence may be regarded as pathological.[18] Again the question raised is whether the individual with such a rhythmic pattern is likely to develop glaucoma at some future time. It is my opinion, based primarily on cross-sectional data and animal experimentation rather than from following a single individual from health to hypertensive disease, that the increase in amplitude of the rhythm in blood pressure is a harbinger of hypertension, and that perhaps the same is true for an increased amplitude in intraocular pressure as a harbinger of glaucoma. (Of course, at present intraocular pressure cannot be self-measured.)

The point to be emphasized is that the monitoring of some rhythms indicative of health can be taught early in life and, in fact, it should be started no later than in high school. If such were done, it is quite likely that the long-term result would be the earlier detection of diseases such as hypertension. At the very least, if the rhythms measured for an individual all fall within the usual reference limits, the data could serve as a reference against which to compare changes which may be encountered in the future. I would assume that if the individual fully understood the importance from the viewpoint of health of monitoring from time to time during his life, he would do so; of course, proper education is of paramount importance to the success of such an endeavor.

Another spin-off of such a program would be that students learning to monitor their own blood pressure would have an impact on their older relatives who may not, in view of our present educational system, have much knowledge of how to monitor blood pressure or even what constitutes abnormal levels. Even if they should already be victims of the disease, the evidence now available suggests that they could, with the aid of their physician, better manage and control the disease.

All of the evidence indicates that chronobiology can play an important role in monitoring and screening of health and thus can aid in the prevention of at least the debilitating stages of a disease such as hypertension or glaucoma. The alternative is to continue the status quo and screen by obtaining samples at single time points. If we choose the latter course, it is unlikely that we can expect any improvement in our present methods of detection, diagnosis and prevention, at least for some diseases. If the individual can be taught to detect hypertension early, the benefit could be significant both for the management of the disease and for the health cost aspect. The argument is sometimes heard that such an approach would create a nation of hypochondriacs; the alternative argument is that ignorance of one's own bodily functions and health may now be contributing significantly to the present numbers of hypochondriacs.

In conclusion, I would like to make certain specific recommendations:

1. In general, for the potential of chronobiology to be fully realized in health, it will be necessary for funding agencies to cooperate. In the past chronobiological research has not been adequately funded. Grant applications that are submitted are, in my opinion, frequently reviewed by persons lacking the essential expertise in the concepts of chronobiology. This opinion is supported by the fact that very few chronobiologists have ever been appointed to appropriate Study Sections - this has been especially true of the health-related Sections. Continuation of funding, when given, has not been stable, often depending upon the composition of the Study Section at the time the application was reviewed for renewal. What is needed urgently is continuous support for the several centers that have demonstrated excellence in this area. A separate Study Section composed of chronobiologists representing the many diverse areas of health should be created to handle all proposals. Until this is done, representation on all Study Sections by chronobiologists with expertise relating to the particular Section should be assured by responsible officers of the National Institutes of Health.

2. Regarding detection and prevention of disease, funding should be provided for at least a five-year period to introduce chronobiological concepts into several high schools around the country in order to obtain data on a larger scale than heretofore has been possible. The protocols used should all be the same and the experimental design should have the benefit of statistical as well as chronobiological expertise. Perhaps the emphasis at first should be on blood pressure. All data obtained should be analyzed by a single center using methods agreed upon as being adequate for analyzing time-series data. One or two other captive populations could also be identified, and similar studies could be carried out on them - preferably these would be older populations. I believe that the cost of such a study could be kept very low over a five-year span; and if the approach seemed promising it could be expanded to a larger section of the populace. The major costs would be for the purchase of an adequate number of suitable instruments, for data analysis, and for supervisory personnel for the over-all project.

Respectfully submitted,
Lawrence E. Scheving
Lawrence E. Scheving, Ph.D.
Secretary-Treasurer, International
Society for Chronobiology

C-418

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PANEL 4

RESEARCH CAPABILITY

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NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES
OCTOBER 3-4, 1978

COMMENTS OF DORIS F. TULCIN, PRESIDENT
CYSTIC FIBROSIS FOUNDATION
6000 Executive Boulevard, Suite 508
Rockville, Maryland 20852

TO THE

PANEL ON RESEARCH CAPABILITY

Maintaining adequate resources to support the research effort has been identified as a crucial problem in the report on Cystic Fibrosis recently prepared by the National Institutes of Health ("Cystic Fibrosis: State of the Art and Directions for Future Research Efforts"), and was also discussed in the reports of the Diabetes Commission, the Huntington's Disease Commission, and other such groups. The recommendations found in the Cystic Fibrosis report are typical, and we urge this panel to consider the following in its deliberations:

A. There is a need to encourage a continuing flow of new investigators into the research community. This need is partially dealt with through the various training programs, which must be maintained and expanded. However, mechanisms to encourage established investigators to pursue areas of greater opportunity outside their present specialties are also required. An expansion of "Pilot and Feasibility" money would assist in both of these efforts, by allowing investigators to establish a trach record in a particular field.

B. An adequate supply of materials for researchers to work with must be assured. Cystic Fibrosis, for example, is a disease found only in humans. There is an urgent need for the development of an animal model that will allow certain types of research to be done which are now impossible. Tissue and serum banks are also necessary so that procedures and research results can be standardized. Data registries of patients can be extremely useful in detecting certain phenomena that could escape the notice of a single clinician who has a limited case load.

C. Encourage the use of core grants or similar mechanisms in the research process. It is widely known that routine

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interaction between scientists will improve the productivity of each of them, and produce results which would be impossible if the individuals were working alone. In some areas, the national research community may be large enough that special "centers" are not necessary. However, in a field such as Cystic Fibrosis, where the available funds and, hence, the available researchers are limited, some core grant or center mechanism will multiply the effectiveness of the work being done.

Another advantage of a core grant approach is that some of the materials development discussed above can be undertaken there, and certain expensive pieces of equipment can be acquired for use in a number of projects, thus reducing the overhead costs of the research.

Finally, the important problem of translating research advances into better patient care can be dealt with effectively through a core grant. These grants most often go to laboratories associated with major clinical facilities, and the researchers either see patients or work closely with those who do. The informal collaboration which occurs can bring care improvement opportunities in advance of the publication of the results of research, thus accelerating the translation of new technologies.

For all these reasons, we believe that core grants or other support for research concentrations is desirable.

WRITTEN TESTIMONY
ON BEHALF OF THE
NATIONAL COUNCIL OF COMMUNITY MENTAL HEALTH CENTERS

This written testimony is made on the behalf of the National Council of Community Mental Health Centers. The National Council has, as its primary purpose, the establishment and maintenance of comprehensive community mental health programs in the United States. It is a membership organization that consists of Federally funded Community Mental Health Centers and other agencies that provide community mental health services. One of the primary interests of the National Council has been in the area of mental health research and program evaluation. It was based upon this interest, that I as Chairman of the Council on Research & Evaluation of the National Council, have been asked to prepare these written statements for your consideration.

One of the main interests of the National Council, especially of the Council on Research & Evaluation, involves the issue of research capabilities. The importance of this issue was increased by the passage of Public Law 94-63, which mandated the Community Mental Health Centers to develop and carry out a wide range of program evaluation activities. The Council on Research & Evaluation of the National Council has examined this issue through several research studies sponsored by the Council or by its members. Results from these studies reflect a glaring lack of manpower and the facilities that are available in mental health centers to carry out essential evaluation and research tasks. Based on our research on this topic, we would like to recommend that the Department of Health, Education and Welfare consider the following suggestions:

1. Increase the support available for the professional training of mental health researchers and program evaluators by (a) funding of special academic programs in the area of mental health program evaluation and (b) providing stipends to individual students to pursue academic careers in mental health research or evaluation.
2. Increase the availability of on-the-job training for mental health professionals as relates to research and evaluation. It is suggested that one important method of doing this is to increase funding available under technical assistance provided by NIMH and ADAMHA Regional Offices.
3. To further the growth of appropriate research and evaluation activities, it is recommended that the appropriate departments of DHEW establish liaison with existing groups responsible for academic and training programs for mental health professions (e.g., Psychiatrists, Psychologists, Social Workers, Nurses) to encourage them to change the existing curriculum in their professions to include increased course material on mental health research and evaluation.
4. It is suggested that serious consideration be given to the development of Community Mental Health Center Research and Evaluation Centers across the United States. It is suggested that these Research & Evaluation Centers be funded so that approximately 25% of their budgets be devoted to research and evaluation. It is further suggested, if possible, these Centers be associated with academic and training institutions. These Research and Evaluation Centers would serve to develop models of research and evaluation approaches that could be used by other CMHC's and/or other mental health organizations.
5. In discussing this subject, it is suggested that we need to turn our

attention to the entire issue of research utilization. In seems imperative that there be a further examination of the type of skills that are needed by researchers and evaluators in the areas of communication and dissemination. It seems quite apparent that the present methods employed to disseminate information are terribly inadequate and one of the prime factors is the lack of skill by researchers and evaluators. It is suggested that this subject needs substantial study and investigation to enable us to develop appropriate training methodologies to incorporate into academic and technical assistance programs.

It is our hope that the information provided to this panel will be of value in your deliberations on this important subject.

Prepared by:
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Chairman
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 Mental Health Centers
2233 Wisconsin Avenue, N.W.
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William R. Barclay, M.D.
American Medical Association
Panel IV
Research Capability

Research Capability

Research capability depends on four factors: Well-trained scientists, an appropriate research environment, reliable scientific communication and adequate financial support.

In the United States, well-trained biomedical research scientists have been recruited from both MD and PhD programs. In both cases the undergraduate training has been partly financed by government grants. The postdoctoral training has been largely supported through government financed fellowships and awards. In the past 30 years government's role in biomedical research has overshadowed all other support, especially in the academic centers. Industry, private philanthropy and voluntary health associations have played a significant but relatively minor part in the massive research effort made in the last quarter century. If government were to withdraw from biomedical research, no alterrative source of support would be readily available. Therefore, government should continue a long-term program to provide training for research scientists.

In the USA, there are several environments favorable to biomedical research. Academic centers, particularly those with schools of medicine, dentistry and veterinary medicine provide an environment to both stimulate and to support research. They provide not only the necessary laboratory space and instrumentation but also a critical mass of scientific talent with whom the investigator can react or from whom he can seek help.

Federal support of fundamental research in academic centers should be continued and increased. Support of research should be separate from the support of such activities as educating physicians and other students in the health professions. Unfortunately, many universities have come to depend on research grants for the support of many of their educational responsibilities that are unrelated to research. A major source of high quality scientific training and biomedical research has been the NIH. No other single organization in any country in the world comes close to matching the work of the institutes. The intramural programs of the NIH should be generously funded and be kept free of political pressures.

Essential to scientific investigation is a reliable system of communication so discoveries and new concepts can be widely disseminated within the scientific community. The United States has fostered a core of scientific journals and meetings that are not matched by any other country. Care must be exercised not to regulate or legislate in a manner that will seriously damage the scientific communication system.

The financial support of research must be ongoing, predictable and reliable. Sources other than government must be encouraged to financially support biomedical research. Tax laws that discourage philanthropy and industry involvement in research should be avoided.

The research capability developed in the United States has paid handsome returns and it merits continued support and encouragement from the public and the government.

National Institute of Health Research Principles Meeting

October 3 & 4, 1978

Presented by: John I. Nurnberger, M.D.
Institute of Psychiatric Research
Department of Psychiatry
Indiana University School of Medicine
Indianapolis, Indiana

Representing: The Society of Biological Psychiatry

Panel for: Research Capability

The few comments I am grateful to make are a direct product of my experience in the development and evaluation of research training capabilities, largely at the postdoctoral level, and exclusively in the areas of behavioral science and psychiatry. I served for three years as a member of the National Institute of Mental Health Postdoctoral Research Training Committee (chairman for one year) and also for a number of years on the Foundation Fund for Research in Psychiatry, which at the time, was dedicated entirely to the support of talented research trainees in the basic biological sciences relevant to behavior and to psychiatry. These experiences, for one thing, confirmed beyond any remotest question an order of priorities in the justification for relevant research training in these areas. Research training in the basic biological sciences germane to psychiatry, obviously, enjoyed a highest priority. The appraisal of numerous candidates and their training setting made clear the obvious conclusion (not always enthusiastically accepted) that no sound and effective clinical postdoctoral research training in psychiatry or the behavioral sciences was possible in the absence of a solid, established, respectful, and continuing base of fundamental scientific endeavor, as well as training.

A scrutiny of many highly effective programs throughout the United States and even outside the continental limits of the United States with regard to the Foundation Fund for Research in Psychiatry activities revealed no exception to the rule that adequate clinical research training could not be pursued without a firm and solid scientific base. This did not, of course, mean that candidates for such training might not, in fact, be primarily clinically trained, and many were. True, an occasional Ph.D.-M.D. candidate entered the field, but most training candidates were not so extraordinarily prepared. The point is that the basic science substrates for such training had to be sufficiently adequate and diversified to provide an adequate and sound basis for clinical research endeavors for both trainer and trainee. Such ideal training in a maximally reinforcing setting demanded a substantial group of M.D., basic science, and behavioral science research investigators as a training cadre. These personnel were often pursuing their training and research activities in an institution or academic department which was identified primarily as clinical and psychiatric. To assure the orderly growth of research training facilities of this type in institutions which do not currently have an adequate basic science foundation in the department of psychiatry or psychiatry and behavioral sciences, some practical changes appear to be justified. Thus, for example, the award of a specific faculty augmentation grant for attracting basic science research personnel to the research and training enterprise would seem to be an effective use of valued and critically short funds. All of us who have served as departmental administrative officers in departments of psychiatry realize that in many of our institutions, particularly medical schools, the highest priority is for the employment of physician-trained personnel with the employment, for example, of Ph.D.'s and other scientifically trained individuals at considerably lower priority, or, in fact, no priority at all. The maintenance of such a complex training climate involves, first of all, an adequate number of training personnel. Many who have attempted the establishment of such a research training program in the past have realized that if they do not enjoy the collaboration of a well-known, well-established, and widely published research training faculty, not only in clinical psychiatry but in the basic behavioral and biological sciences, they simply will not be able to compete for the kinds of trainees, whether Ph.D.'s or M.D.'s, who are absolutely essential to the maintenance of productive research training in the future. Without such personnel, there is no meaning to discussions about problems of recruitment or finding appropriate openings and opportunities for trainees following their training sequences. A substantial number of potential training settings in the United States are, in fact, surprisingly well endowed with excellent, and even inspiring, training personnel in the basic biological and behavioral science areas. Although this situation satisfies the number one priority for such training and, is, of course, essential, it is, by the same token, not sufficient. It is particularly not sufficient in a climate which is strongly medical, as, for example, in a psychiatric research installation, a state hospital, or in an academic department of psychiatry in a medical school. All of us know only too well that the primary value and status is accorded the medical enterprise in a facility of this sort. This has been true ever since psychiatry as a discipline assumed the responsibility for the care of the psychiatrically disturbed.

Now for the much more urgent and critical question of how one establishes and maintains a fruitful setting for such research from the standpoint of research clinical psychiatry in its research components per se. The basic science element, as already indicated, is essential, but it is not sufficient.

A serious effort must be made with help to establish a companion research training enterprise in clinical psychiatry. Appropriate and even inspiring research clinicians who are sufficiently well known as productive investigators are pearls of great price, not available on a wide scale (reflecting an obvious training deficit). The presence and active functioning of a basic and behavioral sciences element does, of course, improve vastly the possibility of recruiting such essential training personnel. Perhaps practical assistance, such as was for so long available through the career and career development psychiatry awards of the National Institute of Health, might be an inspiration here. Perhaps a named or partially supported professorship in clinical psychiatric research for a clinical psychiatrist scientifically trained, rather than, let us say, a behavioral scientist, as was so often the case a decade or more ago, might be a stimuli. The National Institute of Mental Health might provide an important beginning in this area for departments who are otherwise well endowed. This type of support would probably be successful for candidates who are, perhaps, in their middle forties or earlier, and could provide extended years to service. An effective training program of this sort would involve the continuing, collaborative work in research and training of the Ph.D. and the M.D., something which is often difficult to achieve in a medical setting. One experience which often appears to reinforce such an interrelationship is interdisciplinary or cross disciplinary research which involves, for example, a clinically identified and controlled population studied by technical procedures which are beyond the ken of clinical psychiatry. Is it possible for this type of ideal collaboration to occur? Such can occur since it has occurred in as many as a dozen different settings within the past 15 or 20 years. This meeting gives real hope and inspiration to those who have dedicated their lives to the actual training of such people and to training administration that there might be a true and urgently necessary renaissance in this field which is at the very heart of progress in psychiatry.

TESTIMONY BEFORE THE NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

October 3, 1978

(A.) I am Dr. Howard Brinkley from the Department of Zoology, University of Maryland at College Park, Maryland. I am the Washington representative of the Society for the Study of Reproduction, a North American Society with an international membership of over 1500. Our Society's objective is to foster research and training in Reproductive Biology. The Society attains these objectives by sponsoring an annual meeting where research reports and symposia are presented and by publishing the highly acclaimed scientific journal, Biology of Reproduction, in which advances in research are reported.

(B.) I have been authorized by the Board of Directors of the Society for the Study of Reproduction to heartily endorse the principle that "present research capabilities must be sustained and enhanced to assure future health gains".

(C.) Both human and physical resources contribute to the Nation's research capabilities. The numbers of reproductive scientists required to generate new knowledge and the numbers required to develop and apply this knowledge to public health problems is difficult to assess. It has been estimated that the number of reproductive researchers worldwide is about 3,000 with approximately 1600 working in the United States and Canada. By contrast, there were 29,000 U.S. doctoral life scientists engaged in research and development in all sectors as of 1972 (Greep, Koblinsky and Jaffe., Reproduction and Human Welfare: A Challenge to Research. MIT Press, Cambridge, MA, 1976).

(D.) Not only are the reproductive scientists few in number in the

United States, but their expertise is under-utilized because numerous research proposals of scientific merit, which have been approved for funding, have gone unfunded. The Center for Population Research of the National Institute of Child Health and Human Development has reported that it funded only 110 of 440 approved grant applications in fiscal 1977. This represents only 25% of the research grant applications judged to have scientific merit by panels of experts. Much of the under-utilized research capability of these reproductive scientists could be employed in the solution of public health problems if additional funds were made available. However, efficient utilization of existing research capability would not eliminate the need for training people to enter careers in reproduction research.

(E.) Traditionally, training has encompassed predoctoral and postdoctoral study with special programs to provide opportunities for young scientists to further develop their scientific capabilities, for mid-career scientists to renew skills, and for clinically trained individuals to develop into independent investigators. We believe these to be excellent training objectives but we fear they have been compromised in recent years for the following reasons: First, Congress and the Executive Branch of the Federal government have questioned the need for funding the education of biomedical scientists. This led to the dismantling of predoctoral programs previously supported by the National Defense Education Act, National Aeronautics and Space Administration and by the National Institutes of Health. Second, this reduction in predoctoral trainees has been further worsened in recent years by the reduction in the number of teaching assistantships, because of the reduction in undergraduate enrollment at state universities. Third, the inability of the Federal government to develop a comprehensive, uniform and stable policy regarding financial aid to biomedical trainees has made it difficult for reproductive scientists to recruit students to their programs because of the uncertainty of financial support. Fourth, the growth of monies available to the Center for Population Research has been inadequate because of the perception that population was not as urgent a national public health problem as cancer, heart disease, and environmental pollution, among others. This dismal funding picture (25% of approved grants in 1977) forced the CPR staff to divert dollars from training into research grants and contracts even though it had been recommended that the annual funding of training required to strengthen professional capacity and to exploit adequately existing knowledge should be increased 3-4 fold (Greep, Koblinsky and Jaffe, *Reproduction and Human Welfare: A Challenge to Research*. MIT Press, Cambridge, MA., 1976.

(F.) We believe it is imperative to provide an adequate level of long-term support to assure a stability of training programs concerned with fundamental research in reproductive science.

(G.) The research of active reproductive scientists and of those who follow in their footsteps depends on the availability of adequate physical resources. The aging and obsolescence of research facilities and scientific equipment are constant. The need to maintain and replenish these resources is obvious.

(H.) The members of the Society for the Study of Reproduction thank you for the opportunity to testify before this Conference on Health Research Principles.

Dr. Roger A. Gorski, President
SSR
Department of Anatomy
UCLA School of Medicine
Los Angeles, California 90024

Approved by the Board of Directors
Society for the Study of Reproduction
October 2, 1978

TESTIMONY BY DR. J. W. GRISHAM TO THE PANEL ON RESEARCH CAPABILITY

NATIONAL CONFERENCE ON HEALTH RESEARCH PRINICPLES

Bethesda, Maryland - October 3-4, 1978

My name is Joe W. Grisham. I am a physician-educator and basic research scientist at the University of North Carolina at Chapel Hill, where I am Professor and Chairman of the Department of Pathology. In my testimony before the Panel on Research Capability, I represent officially the Association of Pathology Chairmen, an organization of the academic pathology departments of the United States and Canada, whose Research Committee I chair.

Research capability is a complex and fragile property of institutions. It requires talented personnel who possess ingenuity and perseverance, brought together with supporting resources, including adequate equipment and facilities, and a work environment that values and supports scholarly research and provides sufficient time for it to be accomplished. Universities are the performance sites of over seventy percent of the fundamental research conducted in the United States. Recent studies have disclosed that the research capabilities of the major universities are eroding as facilities and equipment age, flow of young investigators decreases, regulations governing acquisition and use of research funds grow more complex, and relationships between universities and government deteriorate. Underlying this decline in research capability is the decreased fiscal support of fundamental research and the resulting responses that government and academic institutions have made to this fiscal stringency.

When high quality, sophisticated instruments are lacking, some lines of inquiry are impossible and in other instances the quality of work suffers. Largely because of inflation, universities can no longer purchase major items of equipment from internal funds. At the same time peer review panels are reluctant to grant appreciable amounts of money for fixed equipment, preferring to stress support of research personnel. This attitude is reflected by statistics showing that the portion of research projects delegated to the purchase of fixed equipment declined by more than fifty percent between 1965 and 1974. Updating and maintenance of existing equipment and replacement of obsolete instruments have been deferred, causing investigators to spend much of their time in repairing aging equipment or in experiencing delays in research projects due to instrument malfunctions. If the vitality of basic research is to be maintained, federal policies on acquisition of fixed equipment must be altered.

The drastically decreased flow of young, highly trained investigators also has handicapped academic research capability. A consistent flow of new talent nourishes and vitalizes research efforts. Following an unprecedented and excessive expansion of federal support for graduate and postdoctoral training in the early sixties, there has been a precipitous decline, as program after program for training scientists has been dismantled when funding was terminated. The important lesson to be gained from this experience is that federal policy toward training of research personnel should be based on long-term commitment to quality rather than on short-term response to temporary fluctuation of the labor market or to changes in political or agency opinion.

Decreased monies for the funding of research projects have led to greater competition for those funds available. The federal government has responded to this increased competition by requiring more elaborate documentation of proposals, by reducing the length of grant periods, and by emphasizing research targets. These shifts in policy have increased greatly unproductive effort and delay in getting projects funded. At the same time the use of grant funds has become more and more tightly regulated, requiring large expenditures of an investigator's time on nonscientific administration and necessitating agency permission for even small budgetary deviations. Such rigidity often prevents the investigator from following new leads that develop after work on a project has begun. Some flexibility is desirable to promote efficiency. The increasing burden imposed on the investigator in acquiring and managing research funds must be lessened by simplifying existing regulations and procedures if efficiency of academic research is to be maintained.

In this climate of decreased support and increased competitiveness and regulation, the entire relationship between universities and the federal government is deteriorating. The original research partnership between government and academic institutions has been replaced by an often acrimonious, adversarial relationship. Federal and academic administrators now have serious disagreements on management issues as diverse as documentation of effort expended on research projects and establishment and justification of indirect overhead charges. The important venture between government and academe in basic research must be returned to a cooperative basis if it is to thrive in the future as in the past.

Specific recommendations to improve research capability are:

1. Funding of facilities and equipment must be restored to the former level of about eleven percent of total research allocations, to allow use of the most capable, sophisticated techniques. Optimally, equipment should be supported from a source separate from that used to fund projects, and requests for equipment should be reviewed by a panel not evaluating scientific merit of research proposals.

2. Support for graduate and postdoctoral fellowships should be increased and their use made less potentially punitive, to restore the needed supply of young investigators.

3. Specially targeted basic research should be reduced drastically, with research initiatives determined by the individual investigator on the basis of his or her expertise and interests.

4. Mechanics of funding should be altered so that more stable funding can be efficiently accomplished and unproductive investigator effort reduced.

5. Regulations pertaining to administration and management of grants should be simplified, without compromising public accountability, to allow highly trained investigators to focus their talents on scientific objectives.

6. Federal and academic administrators must work together as partners, sharing problems on a footing of openness and equality, to reduce the adversarial climate that now poisons this joint venture in fundamental research.

Thank you, Mr. Chairman, for the privilege of presenting these viewpoints.

To: Panel #4, Research Capability

I wish to urge the NIH to use existing programs for planning and evaluating human resources for research and physical facilities, particularly equipment.

The efforts of the Committee established by the National Research Service Act of 1974 are effective and well designed. These efforts have produced annual reports which recommend manpower needs, identify problem areas in research manpower and provide better understanding of the processes by which high quality research manpower is produced. The increased protential of underrepresented ethnic groups and women has been documented. I urge the NIH to use the full capabilities of the NRSA study (available from the National Research Council, Washington, D.C.).

Much effort is currently going into improving the safety and accessibility of existing facilities. This is needed and will improve the nation's research capability.

The resources of universities, research hospitals and the NIH have been stressed in meeting the priorities of safety and access. Recent studies by NIH and NSF reveal major and continuing needs for equipment and specialized facilities. The forward plan for research should recognize the deficit in research capability that has accrued while our resources met the high priorities of safety and access. As we move forward we must seek a balance which assures these goals while promoting sound, high quality, technical capability in equipping and renovating the nation's laboratories.

Robert M Bock

Robert M. Bock

American Society for Biological Chemists

Oct. 3, 1978

John C. Partin, M.D., Research Capability
Program Director, Clinical Research Center, Children's Hospital Research Foundation

PANEL IV: RESEARCH CAPABILITY

Young minds energetically applying the methods of science to unlock the mysteries of nature are the blood and sinew of our national biomedical research capability.

The path to full understanding of natural processes is long, hard and tortuous, and sometimes so narrow or obscure that it can be traversed by only one or a few scientists at a time. The path must be painfully sought out and widened before it can support the traffic demanded by those who wish to arrive at "targeted" destinations. The young or imaginative scientists, the pathfinders, must explore ahead singly and in small groups, sometimes for years and even for generations before the paths of scientific endeavor can be converted to expressways of applied utility.

It is in the universities that these pathfinders must be trained and nurtured until they have chosen a suitable path and become surefooted upon it. It is precisely in the nurture of young scientific investigators where our scientific capability has weakened, and in some cases, decayed.

Both government and private resources will be required to revitalize our national biomedical research capability. The Government must make a major investment in the training of scientists at universities and their medical schools. The science training program must be planned to begin in earnest early in the undergraduate experience. Some form of support must be devised to nurture the young scientists in new and original endeavors at the very beginning of their careers, a a time when current peer review practices deny them access to funding by a process the ponderous nature of which is more suitable for supporting well established research than for supporting fledglings during the critical two to five years that they are getting started.

The development of a solid national research capability in universities requires funding which is constant and predictable. Such funding programs should be developed and promoted in and of themselves, and they should be dissociated from crash targeted projects and programs.

At the medical school level, quality universities should be offered funding which would attract a small but definite trickle of qualified students into science programs, probably for one to two years at the end of their first or second year of medical training.

At the graduate level, programs such as the Biomedical Research Support grant system should be continued and expanded. This valuable program allows individual institutions start-up money for their most promising young talent and for creative programs which are still embryonic.

In Summary: The success of biomedical research depends upon a continuing supply of talented young scientists. Intense national biomedical research will be required for generations, not decades. Planning should take long term national requirements into account.

Most science training and much of the original research must take place in a free atmosphere in universities.

A system of funding must be developed which is predictable, stable and flexible.

A portion of the funding should be allocated as block grants to universities of proven competence. Probably the block grants should involve certain specific functions, such as:

1) Undergraduate science training

2) A scheme to assure that a reasonable proportion of medical students pursue a science track

3) Some form of postgraduate training grant programs for physics, chemistry, mathematics, biology and medicine in which funding of young individuals and new or starter projects is under local control

4. The anti-science attitude prevalent in many medical schools, social and health agencies must be combated.

The scientific method is the backbone of our modern medical accomplishment; the working scientist is the muscle of our effort. Without science, medicine becomes very expensive quackery and a bad long term investment for the American people.

TESTIMONY OF JOSEPH A BELLANTI, M.D., PROFESSOR OF PEDIATRICS AND MICROBIOLOGY, GEORGETOWN UNIVERSITY SCHOOL OF MEDICINE, PRESIDENT-ELECT, SOCIETY FOR PEDIATRIC RESEARCH, BEFORE THE NATIONAL CONFERENCE OF HEALTH RESEARCH PRINCIPLES, PANEL ON RESEARCH CAPABILITY

OCTOBER 3 - 4, 1978

Mr. Chairman, Ladies, and Gentlemen, I appear before you today in behalf of the Society for Pediatric Research, as a Professor of Pediatrics and Microbiology, Editor-in-Chief of the Journal, Pediatric Research, President-elect, Society for Pediatric Research, and investigator, and author of over 150 scientific papers, to present our views on research involving infants and children.

I am pleased to have this opportunity to participate in this conference, since the deliberations and recommendations which emanate from it will have not only immediate consequences but also far reaching sequelae.

In my presentation, I shall attempt to briefly cover the following points:

- the importance of research involving children
- the distinction between "basic" and "applied" research
- the need for new scientists
- the need for renewal of physical facilities to conduct research
- the need for clinical research scientists for technology transfer

The importance of research involving children

In 1900, the infant mortality in this country was 200 per 1000 live births. Of these, 180 were from respiratory infections and diarrhea. Today as a result of better therapeutic measures which resulted in part from research in infants and children, that figure has been reduced to 16.2 per 1000 live births. In the past 10 years, owing to the widespread use of measles vaccine, approximately 23 million cases of measles have been prevented; 2400 lives saved, and 8000 cases of central nervous system damage prevented. Vaccine testing had to be performed in children before widespread efficacy of the vaccine could be established. The same can be said about poliomyelitis, rubella, and mumps. Future research testing which will be conducted in children will include vaccines for the prevention of H. influenzae, hepatitis B, meningococcus and pneumococcus.

Recent years have also witnessed advances in other fields through research in children. Investigation into a number of genetic conditions and inborn errors of metabolism have resulted in better diagnostic and therapeutic approaches to diseases such as phenylketonuria and cystic fibrosis.

There are a number of unsolved problems in pediatrics and therefore, a continuing need for additional research in children in other areas such as nutrition, hematology and oncology, neurology and the behavioral sciences. Not only have these advances been important in themselves, but they have provided the greatest cost effectiveness of any health measure to date. It would be impossible to provide sufficient manpower, for example, for the current health system to say nothing of an expanding health system, if physicians and health professionals had to deal not only with current problems but also with managing those infections, nutritional, biochemical disorders that have been virtually eliminated by medical research.

One of the greatest benefits of research in infants and children is that preventive measures can be instituted at an early age. Further, by identifying antecedents of adult illness in the pediatric age - measures can be instituted to actually prevent the diseases in the elderly.

These are some examples illustrating the fruits of research. It is essential that if we are to continue to advance knowledge that we need to understand the etiology or pathogenesis of disease, to prevent disease, to treat disease, and to cure disease that we understand disease processes. And this requires the need for research in normal children and the study of normal processes as well as the study of disease processes.

The distinction between "basic" and "applied" research

Research in infants and children, as in other age groups, may be divided into: 1) "basic" or fundamental research - that which employs the predictive approach and leads to new knowledge which does not necessarily have any immediate application, and 2) "applied" or clinical research - that which leads to knowledge through the study of patients and which may have more direct clinical application. Obviously this is an artificial separation and both types of research are equally important and should be supported. As will be described below, one of the greatest needs is to encourage the information exchange between these two groups.

The need for new scientists

Having stated the need and the types of research disciplines, it follows that in order to insure a constant flow of new knowledge that there be a stable supply of scientists. One trend today, however, has been an alarming decline in the number of young scientists entering the field of research, a trend which we have also observed in pediatric research. One of the major reasons for this decline has been the lack of stability of research support for young investigators.

We are concerned, therefore, that we are not meeting the needs of research in the field of pediatric research and this trend must be reversed.

The need for renewal of physical facilities to conduct research

Most types of research grants including investigator initiated, program project, and center grants do not include funds for major renovations of physical plant. Medical schools have had to provide such funding previously from federal grants. With the cutback in federal research support of medical schools coupled with inflationary trends, all medical schools, and particularly private medical schools, have felt the economic crunch and have been unable to provide the funds for new facilities. In addition, existing physical plants are decaying and are in need of renovation. The complexity of new research techniques and equipment which require additional space have created a serious crisis! Clearly there is a need for support of research, but also, an equal need for funds to provide the facilities to conduct the research.

The need for clinical research scientists for technology transfer

As described above in the translation of knowledge derived from fundamental research to clinical application, there must be an adequate number of clinical scientists to provide the transfer. Moreover, the training of clinical scientists requires the same rigorous approach as the training of the basic scientist, in the design of experiments, the implementation, and the interpretation of data. In most cases, there is required an even greater requirement for a rigorous approach because of the complexity of clinical research, the need to assure safety and, in the case of pediatric research particularly, the severe restrictions which limit the extent of human experimentation. Current training grants support only basic research training but little or no clinical training. Clearly there must be a reversal of this trend in order to assure the information transfer.

An additional recommendation to facilitate the technology transfer is the need for future support of interdisciplinary types of research. One recent example of this is the Centers for Interdisciplinary Research in Immunologic Diseases (CIRIDS) program of the NIAID in which this transfer of basic knowledge in immunology will occur into areas of clinical immunologic diseases. The scope of this program also extends to transfer of information beyond the institution into the community addressing problems of a much broader socio-economic scope. We would recommend the support of similar types of interdisciplinary research in other areas to facilitate the transfer of basic knowledge into clinical applicability.

Summary

In this brief presentation, I have attempted to make the following recommendations:

- continued need for research of infants and children involving both study of normal and diseased states
- the need for the support of both "basic" and "clinical" research
- the need for training new scientists
- the need for renewal of physical facilities
- the need for more clinical research scientists to facilitate technologic transfer with more support of the interface - facilitated by interdisciplinary approaches.

Statement by Dr. John V. Bergen
President
Philadelphia College of Pharmacy and Science
On Research Capability
National Conference on Health Research Principles
National Institutes of Health
Bethesda, Maryland
October 3, 1978

I am John V. Bergen, Chairman of the Government Affairs Committee of the American Association of Colleges of Pharmacy (AACP). I am the President of the Philadelphia College of Pharmacy and Science, the nation's oldest college of pharmaceutical sciences. My graduate education and research interests are in pharmaceutical chemistry, with emphasis on the chemical analysis of medicinal agents.

AACP genuinely appreciates this opportunity to focus its views on the important role of schools of pharmacy in health research and the needs of these schools if the availability of resources, both physical and human, necessary for the conduct of health research is to be assured.

Many of the nation's 72 accredited schools and colleges of pharmacy have made significant research contributions over the years in pharmaceutics, pharmaceutical and medicinal chemistry, pharmacology, natural product chemistry and pharmacognosy, in the pharmacy economic and administrative sciences, and in related disciplines. With the dynamic transition in recent years to patient-oriented pharmaceutical education, new research emphasis has emerged and developed in analytical pharmaceutical chemistry, pharmacokinetics, and biopharmaceutics.

PHARMACOKINETICS IS THE STUDY OF THE RATE AND EXTENT OF ABSORPTION, DISTRIBUTION, AND ELIMINATION OF DRUGS OR OTHER CHEMICAL SUBSTANCES IN ANIMALS OR HUMANS. THROUGH PHARMACOKINETIC FINDINGS IN CONJUNCTION WITH OTHER PATIENT FACTORS (E.G., THE IMPACT OF ILLNESS AND OTHER INDIVIDUAL CHARACTERISTICS ON RESPONSE TO DRUGS) IT IS POSSIBLE TO DESIGN INDIVIDUAL DOSAGE REGIMENS WHICH OPTIMIZE DRUG THERAPY. BIOPHARMACEUTICS IS THE STUDY OF THE RELATIONSHIP BETWEEN THE PHYSICAL AND CHEMICAL PROPERTIES OF THE DRUG IN A DOSAGE FORM AND THE BLOOD LEVEL OR BIOLOGICAL EFFECT ELICITED AFTER IT IS ADMINISTERED TO ANIMALS OR HUMANS. THE RESULTS OF BIOPHARMACEUTICS EVALUATIONS ALLOW THE PHYSICIAN AND PHARMACIST TO SELECT DRUG PRODUCTS SCIENTIFICALLY ON THE BASIS OF THE TECHNICAL MERIT AND QUALITY OF THOSE PRODUCTS UP TO TIME OF ABSORPTION.

PROPERLY DEVELOPED AND APPLIED, RESEARCH IN THE PHARMACEUTICAL SCIENCE DISCIPLINES CLEARLY CAN CONTRIBUTE TO ACHIEVEMENT OF OUR PUBLIC POLICY PRIORITIES IN HEALTH CARE; NAMELY, IMPROVED PRIMARY CARE OUTCOMES AND COST CONTAINMENT.

OUR OBJECTIVE IS TO MAXIMIZE THESE CONTRIBUTIONS. BUT IT IS DIFFICULT TO BUILD A RESEARCH PROGRAM OF MAXIMUM IMPACT IN THE ABSENCE OF A SOURCE OF STABLE AND FLEXIBLE FUNDS. BECAUSE OF OUR SUBSTANTIALLY SMALLER RESEARCH BASE AS COMPARED TO THAT OF MEDICAL AND CERTAIN OTHER HEALTH PROFESSIONS INSTITUTIONS, COLLEGES OF PHARMACY FIND IT DIFFICULT TO COMPETE IN THE RESEARCH FUNDING ARENA AND TO BUILD SUCH PROGRAMS.

Available figures from two years ago show that our medical colleges averaged $7,600,000 in sponsored research funding, more than 21 percent of the total revenue of these institutions. Funding of sponsored research in our colleges of pharmacy is at a level that is but a small fraction of this.

We believe that our nation's colleges of pharmacy constitute a physical and human resource essential to the total health research effort of this country, and that the present research capabilities of this resource must be enhanced to ensure future health gains. An important element in such enhancement is the availability of a source of stable and flexible research funding. This objective can be accomplished through flexible support of those institutions, regardless of size, which most effectively participate in research in proportion to the size of their total academic undertaking. Our proposal, then, is that the concept for eligibility underlying the Biomedical Research Support (and Development) Programs be reoriented on the basis of the percentage of the total budget of an institution represented by funding of the health science research effort of that institution.

We also wish to underscore the importance of providing opportunities for clinically-trained individuals with demonstrated aptitude for research to develop into independent investigators, as well as for Ph.D.'s in the pharmaceutical sciences to enter clinical and other research disciplines. Because of the development of patient-oriented academic programs in our colleges and evidence of

THE HEALTH OUTCOME AND COST EFFECTIVENESS BENEFITS OF CLINICALLY-ORIENTED PHARMACY SERVICES, THESE TRAINING OPPORTUNITIES ALSO SHOULD BE AVAILABLE TO PHARMACY CLINICIANS AND PHARMACEUTICAL SCIENTISTS. ACCORDINGLY, FUNDS NEED TO BE PROVIDED FOR DEVELOPMENT, SUPPORT, AND EVALUATION OF TRAINING PROGRAMS TO PREPARE CLINICAL SCIENTISTS WHO CAN RELATE THEIR SPECIALIZED SCIENTIFIC KNOWLEDGE TO THE CLINICAL ROLE OF THE PHARMACIST WHILE SERVING ON FACULTIES OF COLLEGES OF PHARMACY AND IN OTHER RESEARCH POSITIONS.

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Name: Robert M. Berne, M.D.
Affiliation: Association of American Medical Colleges
Panel: RESEARCH CAPABILITY

I am Robert M. Berne, Chairman of the AAMC Council of Academic Societies and of the Department of Physiology, University of Virginia. I am pleased to appear before this Panel to present the views of the Association of American Medical Colleges on maintaining and strengthening the biomedical and behavioral research capability of this nation. The Association has provided to the Department extensive, carefully considered remarks on the subjects of research training and the strengthening of the institutes which conduct both research and training. The AAMC position was developed with input from more than 40 professional and academic societies. Because of the severe limitation of time available in which to present our views to this Panel, I must confine myself only to the recommendations of our Association; however, I have sufficient copies of those sections of our Biomedical and Behavioral Research Policy statement which bear on the problem before you so that you may each have a copy at this time to aid your deliberations.

The Federal involvement in training of researchers has, in recent years, reached levels of about 180 million dollars annually. These sums support the training of about 12,000 persons annually - clearly an effort beyond the capability of the private sector to support. Since 1973 programs for the training of new investigators have been marked by uncertainties of purpose and of funding, by impoundment and subsequent release of training funds, and by continued fluctuations in appropriated funds. These uncertainties have been noted by young people contemplating a research career and indications now exist that the pool of future researchers may be in jeopardy. Because research is primarily an activity of young inquiring minds, it is essential to take steps to make research careers more available and attractive to young persons with the talent, motivation and dedication upon whom the continuity and productivity of research depends.

The AAMC has repeatedly urged strong support for biomedical and behavioral research training through the institutional training grant, especially for pre-doctoral trainees in the basic sciences but also for those post-doctoral trainees in the clinical sciences who re reciving their first exposure to research training.

Individual NIH fellowships should continue to be available for trainees of proven research cability who compete on a national level for funding. Efforts must be made to synchronize the application process to the training process and NIH, working with the training institutions, should give high priority to a program of oversight of the training grants to assure a commitment to train only highly qualified trainees, a large fraction of whom should go on to productive academic and research careers. Peer review of the training institutions should be utilized to assure this end.

In the area of research training the Association recommends:

- The Federal government should renew its commitment to both pre- and post-doctoral training of highly qualified research scientists in the biomedical and behavioral sciences.
- The institutional training grants should be recognized as the most appropriate mechanism to provide initial research experiences in either basic or clinical areas.
- The institutional training grant should be the principal means of assuring an adequate supply of research manpower. Such training grants should receive external review of both the trainees and the training sites. Administrative oversight should be employed to insure continuity and quality of training.

- A vigorous program of post-doctoral fellowships should be supported as a valuable adjunct to the institutional training grant.

- The Federal government must make a concerted effort to eliminate instability of funding and poor timing in the training application process.

A special note must be taken of the problems of clinical research training. Despite the importance of their role, the number of physician-scientists applying for and obtaining federal research project support in clinical areas has declined over the last ten years. The reasons for this decline are not apparent at this time but the participation of physician-scientists in applied research is essential for the vitality of the research process. Therefore, the Association recommends:

- Methods should be found to encourage research training and academic careers by physician scientists.

- The possible impact of the payback requirement on reducing the number of clinical science trainees should be examined and other alternatives sought if necessary.

- The Medical Scientist Training Program should be continued and expanded cautiously.

- We believe that it is especially important for the government to realize that large grants seriously impact the institutions which peform the work supported by such grants. Staff must be recurited, space must be created and significant adjustments made in the academic environment. As a matter of principle, therefore, the AAMC suggests that greater recognition be taken by the Federal govenment of the impact upon performer institutions when large grants are initiated or terminated. As a corollary, it is important to establish a mechanism within HEW to coordinate agency support and missions so that the adverse effects of multiple start-ups and terminations are avoided.

Name: Robert M. Berne, M.D.
Affiliation: Association of American Medical Colleges
Panel: RESEARCH CAPABILITY

In order to strengthen the institutions which perform research:

- The AAMC urges increased Federal effort to stabilize research opportunities through the full reimbursement of research costs (including indirect costs and depreciation expenses) and a renewed commitment to the Biomedical Research Support Grant.
- The AAMC recommends funding for the construction and renovation of biomedical and behavioral research facilities, and for the purchase and maintenance of research equipment.

John R. Blinks, M.D.

TESTIMONY FOR THE AMERICAN HEART ASSOCIATION

Conference Convened by the Department of Health, Education and
Welfare Secretary Califano, October 3 and 4, 1978

Panel 4 - Research Capability

Distinguished Members of the Panel:

I am here on behalf of the American Heart Association, in the capacity of Chairman-Elect of the Research Committee of that organization. That Committee, as some of you probably know, is responsible for the continued formulation, management, and evaluation of the National research and research training programs of the American Heart Association. These include the Grant-in-Aid Program, the Career Investigators Program, and the Established Investigators Program, as well as a small research fellowship program. The amount of money that we have available to support these programs is small, and we are never able to fund more than a small proportion of the worthy applications. In agonizing over these applications, the members of the Research Committee are reminded painfully and regularly of the present inadequacy of support for research, research training, and research facilities in this country that has been stressed by almost every speaker so far today. If I say no more about the subject, please do not interpret that as reflecting a lack of concern about the matter, but rather a response to Secretary Califano's request for specific suggestions concerning the allocation of limited research resources.

Several of the previous speakers have pointed out the fact that there is an alarming decline in the number of well-trained young clinicians who are equipping themselves adequately for careers in investigative medicine. The Research Committee of the American Heart Association has noted this trend over the past five or six years, and has now taken a concrete step to try to reverse it by establishing a new program of Clinical Scientist Awards. The extent of our conviction about the need for such a program is underscored by the fact that the funds to establish the program had to be taken from the already underfunded Grant-in-Aid and Established Investigatorship Programs. We cannot afford to make many such awards, and, frankly, we hope that the Clinical Scientist Award Program will serve as a model that will encourage wealthier organizations, such as the National Institutes of Health, to set up similar programs. This hope may not be entirely unrealistic. I believe I am correct in stating that the AHA's Established Investigatorship Program served as a model for the establishment of the Research Career Development Awards by the NIH some 25 years ago.

Clinical Scientist Awards will provide five years of salary support at a realistic level for academically-oriented physicians who will normally have just finished their specialty training at the time of the award. Awardees will spend approximately two years in full-time research training in the laboratory of a carefully selected scientific preceptor anywhere in the world. The sponsoring institution must commit itself to establishing a laboratory for the Clinical Scientist at the time that he or she returns from the research preceptorship, and must indicate that the applicant will be able to spend at least 75% of his time in research for the remainder of the period of the award.

The first applications for Clinical Scientist Awards are now in hand, and we anticipate that between 6 and 10 awards will be made, effective next July 1, 1979. I hope that this experiment will be of interest to the members of the panel, and urge you to follow its progress.

BS-202
10/10/78

Michael D. Lockshin, M.D.
The Hospital for Special Surgery -
Cornell University Medical College
New York, New York

Arthritis Foundation
Professional Education Committee

Address to the Panel on Research Capability

Ladies and gentlemen, my field is arthritis and related diseases. My messages are brief:

(1) Arthritis is a major cause of disability.

(2) Staffing of medical and Allied Health Professional schools with faculty teaching arthritis is inadequate.

(3) By the criteria of manpower retention, sustained researcher productivity, and wide practical application of research findings, arthritis research has in the past been one of the best investments made by the Federal Government.

(4) Fiscal policy now being decided will determine whether an aging cadre of teachers and researchers in arthritis will renew itself, or whether it will dissipate in a vacuum created by Federal indifference.

Let me explain these points.

(1) Arthritis causes disability.

This is an axiom. But there are facts to emphasize. Economic cost includes medical expenses, lost wages, and disability payments. Fifteen percent of Social Security Disability payments go to arthritis victims. Arthritis disability is often life-long, from infancy in many cases, from age 20 or 30 in the majority of cases.

(2) Current human resources in arthritis research and care have for a long time been disastrously low.

Only now, as a result of Federal spending in the 1950s and 1960s, is it possible to imagine acceptable levels of staffing. *A 1975 Arthritis Foundation survey showed that 1 out of 4 American medical schools had no faculty teaching arthritis.* Graduates of these schools were and are ill-prepared to treat this commonest of complaints! Arthritis Foundation Committees have actively assisted medical schools to improve this situation. But gains in one place have been met by losses elsewhere.

Consider the story of a colleague of mine. He is a well-trained, imaginative, and productive researcher. He was recently appointed head of a one-man rheumatology unit at a well known medical school, a school which had not had an arthritis unit. He was told, "Recruit your own staff. We'll pay you for 2 years. Then you generate your own money." But arthritis clinics are largely out-patient, therefore unprofitable. Arthritis is chronic, not dramatic. It doesn't capture the large patient care fees of, for instance, cardiac surgery. This rheumatologist, young and not established, did not compete successfully for training and research awards against more senior, more established investigators. Although he had many potential trainees and a viable program, his medical school could not support the trainees from internal funds. After 3 years, frustrated, he abandoned his position to enter private practice.

His medical school is again without a rheumatology unit or faculty. *Federal research and training grants could have kept this and other arthritis centers alive now, as these grants did in the 1960s.*

(3) Past arthritis grants have been a good investment.

Seventy percent of persons trained with Federal grants in arthritis *have remained in faculty and investigative positions* - higher than in any other professional group! This is excellent value for the dollar! These people train the health care professionals of tomorrow. And there is still a lack, there is still a need, for additional rheumatology faculty. Unlike cardiology, unlike gastroenterology, surgery, and other fields, rheumatology is still very understaffed. But since neither patient care income nor medical school uncommitted funds can support this potential faculty, *stable* Federal research grant support is necessary to guarantee that dollars previously well spent will remain so.

Categorical arthritis money is well spent in other ways. Arthritis research is vastly multidisciplinary. Biochemistry, anatomy, immunology, geriatrics, biomechanics, genetics, microbiology - are all disciplines legitimately subsumed by the concept, arthritis. Arthritis immunology of yesterday is today's cancer immunology. The genetics of spinal arthritis has been the magic key for studies of myriad different diseases. The findings of arthritis research have reached far beyond the musculoskeletal system.

(4) There is a danger of a vacuum of researchers and teachers.

Only 3 of 10 approved - judged worthy of support - applications in arthritis are funded. The last well-funded generation of arthritis workers is past the age of 40. The next generation, like the young rheumatologist I mentioned, is discouraged and withdrawing from competition. If those arthritis specialists now ready to enter a lifetime commitment to research and teaching remain discouraged, the 1990s will be deprived of new ideas and of new trainers of the health care professionals.

At that point, Federal indifference will have purchased at high cost, in dollars and human suffering, the continued tolerance of long-term disability, when it might have bought, at the least, improved and uniform professional care, and at the most, concepts that lead to the prevention or cure of arthritis.

American College of Preventive Medicine
Association of Teachers of Preventive Medicine

I'm David L. Rabin, Professor and Acting Chairman of the Department of Community and Family Medicine at Georgetown University School of Medicine. Today I am representing the ACPM and ATPM.

The most challenging problem of medicine today is not how to diagnose and treat disease,but how to apply what is known and to prevent disease. Despite this, examination of current priorities in health care training and research reveals an overwhelming emphasis on medical science rather than on technology transfer or preventive care. In the past 30 years research in the biomedical sciences was necessary to advance the state of medical knowledge. This investment of time and resources has paid off, but we will fully reap this benefit when this biomedical knowledge is applied, in a preventive manner, to the general population to prevent onset of disease and to slow its progress.

Our greatest priority now is for research in preventive medicine. Research should now be conducted into how current knowledge can be applied to population. Preventive Medicine Departments are new and small and we can't even begin to address research needs in preventive medicine without the faculty to do the research and teach potential practitioners.

The medical education system is the major determinant of how medical knowledge is delivered through the training of physician and non-physician medical manpower. In turn, the Federal Government can, and has historically, played a major role in the directions taken by our medical schools through its allocation of research and training dollars. The large sums of money allocated after World War II to the biomedical sciences were responsible for the current medical school emphasis on the basic sciences and medical technology. Research monies influence both the number of medical school faculty involved in a given area and their level of expertise. It is felt that teachers who double as researchers in their field tend to have a higher level of competence than those who do not. It would follow that through the allocation of research funds to specific areas in the prevention field, the Federal Government could bring about a shift in medical school curricula to these areas. Increasing the exposure of medical students to preventive aspects of medical science would have the effect of increasing the number of students interested and thus willing to specialize in these areas. Paradoxically, at a time when the Federal Government is crying for application of what is known about preventing disease progression, health care services research money has been reduced by 50% in seven years and constitutes a paltry 1/2 of 1% of all medical research money.

Due to Federal financial neglect, preventive medicine is suffering from insufficient research, faculty and students. While many areas of preventive medicine can be studied in schools of public health, these schools cannot effect the health care delivered by physicians now or in the future. It is essential that medical schools develop expertise in these areas in order to prepare future medical manpower to prevent disease and to prevent complications of established diseases. Physicians deliver most health care and can most effectively practice the principles of preventive medicine. The Federal Government must change its funding priorities to reflect its concern for the prevention of disease as well as curing disease.

While more emphasis needs to be placed on research and technology transfer to preventive medicine in general, within preventive medicine there are specific fields which also need Federal attention. Specifically, new research monies should be directed to environmental health, occupational health, nutrition, epidemiology, and the behavioral sciences. Research monies applied to these areas would have the ripple effect of altering the course of disease nationwide. For instance, the current emphasis on acute hosptial care diverts medical students from understanding predisposing factors in disease such as nutrition. Improper nutrition is thought to be associated with the development of many cancers and cardiovascular disease, the two major causes of death and disease in the country. Yet, in only 19% of medical schools is there required teaching in nutrition. Similarly persuasive arguments can be made for emphasis onthe other areas of preventive medicine such as environmental health, occupational health and epidemiology. Additionally, funding in the behavioral sciences could help familiarize students with specific tools necessary to help alter the behavior of the population.

The need for a shift in national manpower funding priorities is clearly seen in the paucity of doctors in the field of preventive medicine. Of the 330,266 practicing physicians in 1974, only 758 listed their specialty as general preventive medicine and 2,695 listed public health. Most medical schools have little curriculum time devoted to preventive medicine and twenty medical schools have no formal programs in preventive medicine. Most preventive medicine departments suffer from understaffing and minimal support. In preventive medicine residencies the outlook is even worse. These residencies have difficulty attracting medical students because of the lack of exposure to the subject in medical school and because they offer poorer salaries than other residencies and, in fact, often require the resident to pay tuition. These factors, coupled with the fact that residents go into salaried positions for careers, act as a deterrent to potential residents. Thus, there is a need not only for support of preventive medicine programs within medical schools, but for residencies also and their enrollees.

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The specific fields of preventive medicine are new and manpower statistics are generally not available. However, manpower availability and need are known for the field of epidemiology and can be applied to the other specific areas. The current supply of epidemiologists is 500, of whom 300 are physicians. This supply stands in stark contrast to the estimated need, which is from a conservative 2,500 up to 8,000 medically trained epidemiologists. Once again, this undersupply of manpower can be traced to current medical education. While in 1979, 75% of medical schools offered at least one course in epidemiology, this often involved a brief introduction in a more general Preventive Medicine survey course. In 1977, there were only 78 institutional training grants available in this area and 20 residency training programs, with a total of 54 positions,not all of which were filled. In 1975, there were also only 35 doctoral candidates in epidemiology in schools of public health. Clearly, current capacity cannot even begin to meet the need in this area.

If Federal money would be given for research and technology application in preventive medicine and its associated areas, a positive cycle would begin. Nonexistent and understaffed Departments of Preventive Medicine could expand and teach more students, and new and better faculty could be trained and attracted. Research could be conducted into the appropriate and most effective application of preventive medicine and technology to the population in general.

In light of these arguments, several recommendations appear warranted. First, we need a major reallocation of Federal research funds to Departments of Preventive Medicine and associated specialties to develop research capacities in the country's medical schools. This money would create the environment which would attract and maintain competent research manpower. This core could then train the next generation of research workers. These monies should be used to provide stable, long-term support for established research units in the fields of epidemiology and health care research, and to develop new research capability in occupational medicine, nutrition, and environmental health. Second, Federal seed money is needed to start Departments of Preventive Medicine at medical schools where they do not exist now. Money is also needed to train new faculty in the several disciplines of Preventive Medicine. And third, we need financial support for residency programs and residents, post-graduate teaching of researchers, and continuing education for established practitioners who had little exposure to this area in medical school.

Documentation of the arguments presented here will be presented in a short paper following this conference.

A DISTURBING TREND IN BIOMEDICAL RESEARCH CAPABILITY

MELVIN E. JENKINS, M.D.

MR. CHAIRMAN, PANEL MEMBERS AND GUESTS: I APPEAR BEFORE YOU TODAY TO EXPRESS PERSONAL CONCERNS AND OBSERVATIONS ON SOME TRENDS IN BIOMEDICAL RESEARCH CAPABILITY. THESE ARE BASED ON MY ACTIVE ROLE OVER THE PAST 25 YEARS IN THE FIELD OF MEDICINE BOTH AS A TEACHER AND A RESEARCHER.

FOR THE PAST FIVE YEARS, I HAVE SERVED AS CHAIRMAN OF THE DEPARTMENT OF PEDIATRICS AND CHILD HEALTH AT HOWARD UNIVERSITY COLLEGE OF MEDICINE. BEFORE ASSUMING THE CHAIRMANSHIP AT HOWARD, I DEVELOPED AND DIRECTED THE PEDIATRIC ENDOCRINOLOGY PROGRAM AT THE UNIVERSITY OF NEBRASKA SCHOOL OF MEDICINE AND WAS PROFESSOR AND VICE-CHAIRMAN OF THE DEPARTMENT OF PEDIATRICS THERE. IN ADDITION, I AM CURRENTLY A MEMBER OF THE NATIONAL ADVISORY RESEARCH RESOURCES COUNCIL OF THE NATIONAL INSTITUTES OF HEALTH AND ALSO CHAIRMAN OF THE GENERAL CLINICAL RESEARCH CENTERS PROGRAM GROUP OF THAT COUNCIL.

DURING THIS PRESENTATION I WISH TO DIRECT OUR ATTENTION TO ONE MAJOR RESEARCH RESOURCE WHICH APPEARS TO BE RAPIDLY DWINDLING, THAT IS, THE YOUNG CLINICAL INVESTIGATOR. THIS IS A MOST SERIOUS PROBLEM WHICH REQUIRES URGENT ATTENTION. NO EFFICIENT AND EFFECTIVE HEALTH SYSTEM CAN MAINTAIN ITSELF WITHOUT CONTINUED RESEARCH INPUT. I SUBMIT TO YOU THAT THE DECLINE IN TRAINING OPPORTUNITIES FOR YOUNG INVESTIGATORS HAS RESULTED IN A DRASTIC REDUCTION IN FUTURE BIOMEDICAL RESEARCHERS. FURTHERMORE, IT IS MY BELIEF THAT A SUBSTANTIAL INCREASE IN

Federal support for research training can significantly help bolster the supply of young investigators. In this connection, I would also like to point to the existence of an untapped significant pool of potential biomedical researchers among racial minorities and women.

Major improvements in health delivery have resulted from research contributions. Smallpox, yellow fever, plague and other epidemics of the past which devastated large populations are now almost extinct largely because of early crude research generated methods. In our generation, dibilitating and sometimes lethal diseases such as poliomyelitis, measles and rubella have been contained by vaccines which evolved from basic and applied research. Clinical investigators supported by public and private funds were absolutely essential to breakthroughs necessary to develop the materials and methods to conquer these serious afflictions both for Americans and for peoples throughout the world.

In the future, heart disease, cancer, stroke and mental illness remain to be harnessed. Maintenance of a cadre of productive biomedical researchers must be facilitated in order to continue improvements in health care techniques which will lead to prevention or cures of these disorders.

I REPEAT THAT AT THE HEART OF BIOMEDICAL RESEARCH IS THE RESEARCHER. A CONTINUED INFUSION OF NEW, YOUNG WELL-TRAINED BIOMEDICAL RESEARCHERS CAN MOST EFFECTIVELY MAINTAIN THE MOST VITAL COMPONENTS OF RESEARCH CAPABILITY - THE RESEARCH SCIENTIST.

WHILE THE RETRENCHMENT OF FEDERAL SUPPORTED RESEARCH TRAINING IS A PRIME CONTRIBUTOR TO THE INCREASING DEARTH OF CLINICAL INVESTIGATORS, I AM NOT UNAWARE OF OTHER INFLUENCES THAT ARE ALSO PRESENT. IN AN ATMOSPHERE OF DECLINING CONSTANT DOLLARS FOR RESEARCH, ALREADY ESTABLISHED INVESTIGATORS HAVE RECEIVED DISPROPORTIONATE COMPETITIVE RESEARCH FUNDS AND LARGER RESEARCH ORIENTED UNIVERSITIES ATTRACT RELATIVELY MORE RESEARCH AND TRAINING AWARDS.

TODAY, BIOMEDICAL RESEARCH CAN BE FINANCIALLY MUCH LESS ATTRACTIVE THAN MORE LUCRATIVE PRACTICE CAREERS FOR YOUNG PHYSICIANS. SOCIAL AND ECONOMIC DEMANDS ON YOUNG PHYSICIANS IN TRAINING HAVE OFTEN DISCOURAGED LONG TERM RESEARCH CAREERS. FEWER RESEARCH TEACHING POSITIONS ARE BEING FUNDED IN MANY MEDICAL SCHOOLS. THESE TRENDS MUST BE REVERSED AND THE DEPARTMENT OF HEALTH, EDUCATION AND WELFARE HAS THE OBLIGATION AND RESPONSIBILITY TO TAKE THE LEAD IN CONTAINING THE DECLINE IN YOUNG CLINICAL INVESTIGATORS.

It is my opinion that our failure to motivate and to train young biomedical clinical investigators is a serious threat to biomedical research and ultimately to competitive health care delivery in this country. A generation of biomedical researchers may have already been lost! Related to the problem of a decline in young clinical investigators is the status of research training opportunities for minorities and women. Currently only two percent of this country's physicians for example, and even less than two percent of biomedical researchers are Black.

While programs such as Minority Access to Research Careers and the Minority Biomedical Research Awards are tangible efforts to meet this shortage, much more is needed. Women indeed represent another vibrant and untapped population segment from which competitive researchers can be drawn.

I am encouraged by the commitment of the Department of Health, Education and Welfare to long range research principles. Research capability however, is dependent on a strong cadre of biomedical investigators including clinical investigators.

Research training programs for potential biomedical researches must be supported by the Department of Health, EDUCATION AND WELFARE. YOUNG CLINICAL INVESTIGATORS ARE ESSENTIAL TO IMPROVEMENTS IN OUR HEALTH DELIVERY SYSTEM TO A MORE COMPETITIVE AND EFFECTIVE LEVEL. THE HEALTH NEEDS OF AMERICANS CANNOT BE FULLY MET IF BIOMEDICAL RESEARCH TRAINING IS NOT STABILIZED.

THANK YOU!

RESEARCH CAPABILITY AT SCHOOLS OF OSTEOPATHIC MEDICINE

Robert W. Gracy, Ph.D.
North Texas State University Health Science Center/Texas College of Osteopathic Medicine
Representing: The American Association of Colleges of Osteopathic Medicine
Panel 4: Research Capability

The research potential of the schools of osteopathic medicine has increased dramatically in the past five years for two principal reasons. Firstly, there has been a rapid growth in the number of such schools, and secondly, there has been the increased state-financial support for our schools and affiliation with established universities.

Prior to 1970, there were only five schools of osteopathic medicine. These were privately-funded institutions with relatively small faculties, heavy teaching commitments, and limited physical facilities. Since 1970, the number of schools of osteopathic medicine has increased to fourteen with an accompanying increase in the number of graduating osteopathic physicians, faculties, and facilities.

In the past our schools of osteopathic medicine succeeded in developing strong programs of health care delivery primarily based on the training of family physicians. However, the long-term educational investment in the training of future medical educators and researchers has lagged behind the mainstream of most medical education in this country. The educational philosophy of osteopathic medicine fully recognizes that the development of a strong research base is inseparable from clinical application and practice. However, this research capability is only recently beginning to be realized.

It is our belief that this potential should be developed as an integral part of the national medical research effort.

The recent trend toward state support and university affiliation of the schools of osteopathic medicine has markedly increased our research potential. Seven of the nine new schools are either totally state supported and/or directly affiliated with established universities. The added support for faculty, equipment, operation costs, and construction has placed these institutions in the same category as other developing state-supported medical schools in this country.

State support and university affiliation have had many other positive effects, not the least of which has been the enhanced capability for recruiting outstanding young scientists. The growth and development of these institutions at a time when there is a large number of highly qualified and experienced young scientists on the job market has made it possible to recruit new faculties with research experience not heretofore possible. Other advantages such as graduate and postgraduate research programs, the potential for the combined D.O.-Ph.D. degree, the utilization of established research faculties and major items of scientific equipment all are making a major impact on the development of this research potential.

Schools of osteopathic medicine, with their tradition of training physicians in family practice can provide an important element to the spectrum of medical research which has largely been neglected in the past. On the patient-care level, the family physician has several research advantages, such as direct experience with primary care of an unselected population and the opportunity for long-term monitoring of epidermological, social, and behavioral problems. The research-oriented family physician also has the opportunity to evaluate health maintenance, preventative procedures, and the long-term effectiveness of diagnostic and therapeutic methods.

How can we maximally develop and utilize the research potential of our schools of osteopathic medicine? Federal support for new equipment and capital expenditures is essential to all developing institutions. The individual investigator-initiated grant provides the single most important mechanism for the development of our research potential, and we highly endorse it. A major deficiency at many of our osteopathic medical institutions is the paucity of clinical faculty with research experience. Programs which encourage clinical faculty to become more involved in fundamental research, and programs which encourage basic researchers to become more aware of acute and chronic medical problems are needed. Examples of such programs which can accelerate this research potential include the Research Career Development Awards, the Biomedical Research Development Grants, Postdoctoral Training Grants, and support for the combined D.O.-Ph.D. degrees. Support for continuing medical education programs is also necessary to bring basic research discoveries into clinical practice in a minimal time.

We are highly supportive of the idea that diversity of efforts among all research components of the biomedical community is, in the long run, in the best interest of the country. We believe that the colleges of osteopathic medicine provide an important developing research potential which can play a significant role in biomedical research and health care-delivery in this country.

STATEMENT ON RESEARCH CAPABILITY

WILLIAM J. WILLIAMS, M.D.
DEPARTMENT OF MEDICINE, UPSTATE MEDICAL CENTER
STATE UNIVERSITY OF NEW YORK
OCTOBER 3,1978

I would place the issue of assuring the availabilty of human resources as the first priority in developing a national policy on health research. In considering the availability of human resources, the most obvious facet is the training of new investigators, but equally important is the encouragement of independence of already trained individuals, and provision of support for innovative research, by funding both newly trained investigators and new ideas.

The spectacular growth of the biomedical research enterprise in this country is in no small way related to the generous funding of research training in the decade beginning in the late fifties. This development has been criticized as inefficient, but no one can say it was ineffective. Brilliant work in large quantity has been, and is being, produced by the graduates of these training programs. In recent years support for training has been severely truncated by decisions based on budgetary arguments that such training is not an acceptable public responsibility and that the yield of committed investigators must approach 100%. Many of the societal problems which could be [redacted] considered justification for diversion of funds from medical research are intimately related to health problems which can only be solved by research. My view is that extensive support of training programs is the best way to maintain a research enterprise which ultimately will provide solutions to these problems.

I, therefore, believe that a national health research policy must define continuing, stable support for research training as a first priority. Opportunities must be provided for support of sufficient research training for interested individuals to develop independent capability. This need is presently being approached by Research Fellowships, Clinical Investigator Awards, and Research Career Development Awards. These forms of support provide sequential opportunities for research training and experience, beginning with the initial efforts of new graduates (Research Fellowships), continuing with advanced work under guidance (Clinical Investigator Award), and ending with an opportunity to develop the sophisticated skills of an independent investigator (Research Career Development Award). A national research policy should also recognize the utility of the so-called Institutional Training Grant, which permits the program director to appoint trainees at the Research Fellowship level without central review. These instruments have been valuable and effective, but under current policies they are limited in number and unevenly distributed among disciplines, and their very existance is constantly threatened.

The quality of these training programs can be well controlled by careful monitoring, including reasonable assignment of the number of trainees appointed to each. The "payback" provision which requires a period of public service or financial reimbursement if trainees do not continue in research, may be an effective control mechanism, but, if retained, must be clearly defined. Up to now that concept has been vague at best, and the uncertainties surrounding it have been a major impediment to recruitment of research trainees.

The problems caused by present limitations on the total level of funding for research training are compounded by the current intermittent emphasis on particular areas of such training. The training capabilities in a particular area of research are somewhat malleable, but the present [redacted] practices, based on disease emphasis, distort the system excessively and could result in ineffective and inefficient expenditures. I would strongly advocate that the level of expenditure for training in areas of special disease emphasis be based on objective estimates of training availability within an adequately funded, totidisciplinary research training policy.

The public benefits from training programs largely as a consequence of the accomplishments of the independent investigators produced by such programs. It is obviously necessary to permit such people to investigate independently if public benefit is to be realized. This means to me that a national health research policy must recognize the need for adequate support for investigator initiated research. This is not to say that large, multifaceted research efforts should be eliminated, but rather that there should be a policy which encourages a sufficient number of individual investigators to undertake original, independent study of scientifically meritorious problems. Such support can be expected not only to yield a continuing supply of new information in diverse fields, but also, more importantly, to permit full flowering of the research capabilities of the investigators.

Finally, along the same lines, I think continuation of the Biomedical Research Support Grant program has an important role in assuring maintenance of the research enterprise. These funds, awarded at the local level to new investigators or to new projects of established investigators, have an extremely valuable fostering influence on medical research.

These funds permit young scientists to develop their independent work to a point where it is competitive for more formal research funding, and are crucial for the success of such individuals involved in highly competitive fields, or working in areas which do not coincide with the emphasis currently in vogue.

The use of these funds by experienced investigators to initiate innovative inquiries has been equally valuable. The need for "seed money" has, for example, been recognized in the Diabetes Research and Training Center program by the establishment of feasibility or pilot studies as integral components of the centers. The opportunities afforded by such funding should be available over a broad range of disciplines, and this need can be met by a policy recognizing the essentiality of such an instrument.

In summary, a successful national health research policy must nurture research at its source, the young men and women who dedicate their careers to investigation. They must have the opportunity to learn, experiment and discover, and the public will benefit from these efforts in direct proportion to the support provided.

NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

PUBLIC TESTIMONY

NAME: J. H. M. Henderson

INSTITUTION: Tuskegee Institute

PANEL: Research Capability

Research Capability of Minorities and Minority Institutions

J. H. M. Henderson,[1]
Chairman
Minority Biomedical Support
Program Directors Organization

The first American Black to be awarded the Ph.D. degree was Edward Alexander Bouchet. This was just over 100 years ago in 1876. The institution awarding the degree was Yale University. Only one other Black earned a Ph.D. degree during the next 24 years. During the next 30 years -- between 1900 and 1930 -- only 13 other Blacks achieved the Ph.D. degree.

Since that date increasing numbers of Blacks and other minorities have earned the Ph.D. degree. According to the National Academy of Sciences by 1973 minorities accounted for about 4000 living Ph.D.'s out of nearly 200,000 -- a mere 2% of all Ph.D. holders in science and engineering.

At the bachelor's degree level of 104,000 degrees in the natural sciences and mathematics during 1973-74, only 13,310 -- or ca. 13% -- went to minorities and the majority of these were awarded from Black institutions.

During that same time 6,609 Ph.D.'s were awarded in the same fields of which only 240 -- or 4% -- were awarded to minority students.

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[1] Dr. Henderson is a Senior Research Professor of Biology and Chairman of the Natural Science Division of Tuskegee Institute. He is former Director of the Carver Research Foundation of Tuskegee Institute. He is the Program Director of the MBS Program of Tuskegee Institute.

In other words a ratio of one out of every 14 whites who received B.S. degrees in these fields comparably completed the Ph.D. degree. The same ratio for minorities was one out of 55.

Much of the cause for this is not solely academic scholarship and achievement, but lack of personal finance, institutional deficits in technical facilities and equipment, especially among minority institutions — thus a lack of opportunity to obtain a doctoral degree essential for the pursuit of biomedical research.

What was the basic cause which brought on this effect? During the five-year period between 1969-1973 eligible minority institutions on mainland U.S. received less than 2 million dollars in research grants from NIH out of 700 hundred million dollars awarded annually -- less than 0.3%! And of this amount 80% went to the two predominately Black medical schools, Howard and Meharry. Out of 20,000 competing grants, 54 (0.25%) went to mainly the same two institutions.

In 1969, 46 major institutions received more than one million dollars in research training grant awards from NIH. Ten of these institutions had never awarded a science Ph.D. degree to a Black; only 11 of these institutions had awarded to Blacks as many as 10 Ph.D.'s in all fields of science combined. The record for Hispanics and Native Americans is even worse.

Therefore it was most logical and timely -- if not too little, too late — when President Nixon in his annual message to Congress in 1971 stated: "...black institutions are faced with a historic inadequacy of resources. To help these institutions compete for students and faculty with other colleges and universities, the combined help of government at all levels, other institutions of higher learning, and the private sector must be summoned..."

In July of that year the Senate Appropriations Committee called for the General Research Branch, Division of Research Resources, NIH to initiate a biomedical research and research training program for the predominately Black colleges during fiscal year 1972 at a level of 2 million dollars.

At that time 38 minority institutions, mostly Black and in the South, were awarded the 2 million dollars. (The program was initially called the Minority Schools Biomedical Support Program — MSBS.)

In 1977, with 80 institutions sharing in the program, the appropriation had increased to 9.7 million dollars; in FY 1978 the appropriation was almost 10.8 million dollars; for FY 1979 it is 14.6 million dollars. The large increase of approximately 4 million dollars is for indirect costs, which is being included in these awards for the first time -- an item long overdue to institutions which are sorely in need for such funds.

Donald Frederickson, NIH Director, at the annual MBS Symposium in 1977 at Xavier University in New Orleans, conveyed recent remarks by HEW Secretary, Joseph Califano, who told NIH staff that they could not be free from human concern or from pressures he would impose to provide minorities with equal opportunities in biomedical research. Frederickson said Califano encouraged NIH to use its leverage with the private sector and with universities to enlarge the pool of minorities available for top jobs in biomedical research.

What has been the impact of this effort to improve the minority participation in the mainstream of biomedical research? In 1973 -- the first full year of the program -- 250 students and faculty attended the first symposium at Xavier University in New Orleans and presented 76 papers. In 1974 these figures were 470 attendants and 165 papers; in 1975, 900 and 280, respectively; in 1976, 1300 and 370, respectively. In 1977 there were 1350 scientists representing 93 colleges who presented 350 scientific research papers in biochemistry, microbiology, chemistry, physiology, pharmacology, parasitology, psychology, and other biomedical research areas.

What has been the "Fallout" from this emphasis or accentuation of emphasis on biomedical research in minority schools and for minority scientists?

In 1975 among the 75 grantee institutions, 73.7% of the graduating MBS participants went on to advanced degrees as compared to 18% of all science graduates at these institutions. Out of 377 science graduates who went to medical school from grantee institutions, 116 (29%) were MBS participants. Of the 480 students who enrolled in graduate schools, 120 (30%) were MBS students.

What has been the effect on minority institutions due to the MBS program? At one institution (a consortium) in 1976, 75 papers were published by MBS participants and NIH Research Career Development Awards and other grant support have been achieved. This same group of institutions was recently awarded a 2.7 million dollar grant from a federal agency to establish a regional center for (research) resources in science and engineering.

In yet another institution no biomedical research program had existed prior to the MBS Program, due to heavy teaching loads and lack of research facilities. Because of MBS funds, the institution has developed a strong research program and has been able to attract additional research funds, including an NIH Research Center Development award.

And finally, as a result of the MBS Program, MBS grantees have submitted 204 applications through 1977 and of these 127 have been approved with a total of support figure of 3.5 million dollars.

It is obvious that the largest pool of biomedical research capability potential resides in the minority groups -- young and not so young -- in this country. Therefore, it is recommended -- and indeed urged -- that HEW and NIH continue and increase its support to these groups -- minorities and minority institutions.

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William N. Kelley, M.D.

Professor and Chairman, Department of Internal Medicine

University of Michigan Medical School

Ann Arbor, Michigan

PANEL 4: Research Capability

I am William Kelley, Professor and Chairman of the Department of Internal Medicine at the University of Michigan Medical School in Ann Arbor. I am President-elect of the American Federation for Clinical Research, a current member of the Metabolism Study Section, and past-chairman of the ad hoc National Institutes of Health Arthritis Center Study Section. I am testifying before you today on behalf of the American Federation for Clinical Research.

I believe each member of this distinguished panel is well aware of the impending crisis directly related to our failure to attract a sufficient number of talented young physicians to enter an academic career. There are many reasons for this, some quite complex and irreversible. There are, nonetheless, some relatively simple means of enhancing the attractiveness and feasibility of a research career which we believe could have a substantial impact at little cost. While there are many examples upon which we could focus, in the brief time allotted to me this morning I would like to comment on one approach for your consideration.

The AFCR was generally pleased with the provisions included in the renewal of the National Research Service Awards. We would encourage greater funding and emphasis on the Institutional Awards. In addition, we urge for a modification in the payback provision. The payback provision poses relatively few difficulties for the Ph.D. receiving research training. However, for the physician research trainee we believe the payback provision is exerting a detrimental influence. The basis for this assertion is a recent survey of clinical research training conducted by the Association of American Medical Colleges for the National Research Council. We recognize that in the past some individuals who received Federal research training support have gone directly into clinical practice. We support efforts to eliminate this situation but we are more concerned that existing payback requirements discourage young physicians from entering academic careers and pose an additional barrier to individuals whose ability to perform research in untried.

The fact that it is difficult to predict in advance who will succeed in research suggests that more researchers need to enter training than will be needed, particularly in the clinical sciences. To require those physician trainees who were subsequently found to have no talent for research to remain in research or even teaching careers, through imposition of payback requirements, may be truly counter-productive and a waste of money.

William N. Kelley, M.D.
Professor and Chairman, Department of Internal Medicine
University of Michigan Medical School
Ann Arbor, Michigan

PANEL 4: Research Capability

We believe that an alterative to direct payback by the trainee can be designed which will assure that the objective of training for careers in research and academic medicine is attained. In effect we recommend that the training institutions, the program directors, and prospective trainees share in the responsibility that the process of trainee selection and the nature of the training program serve only that purpose.

We wish to offer the following proposal for your consideration:

"NEW TRAINING GRANT AWARDS

For new institutional training grant awards, the payback provision shall continue for the first 2 years of the award. After the first 2 years, the project director may elect an alterate proposal -- option A -- as described below.

(a) The trainee would not personally be bound to the payback provision.

(b) The program director of each institutional training grant in clinical sciences choosing option A must select trainees and their training curricula very carefully and must assure that the majority of graduates of each program engage in research or teaching activities for a period at least equal to that for which Federal research training support was received under NRSA. 'Research or teaching activities' are now defined in the law as 'health research or teaching or any combination thereof in accordance with usual patterns of academic employment,' section 472 (1) (A)(i).

(c) The program director of each institutional training grant choosing option A shall furnish to the NIH on July 15 of each years the name, address, and current activities -- for example, research, practice, teaching -- of each program graduate for the previous 5 years.

(d) The NIH shall monitor very carefully the information furnished to it to assure that each program selecting option A places at least a majority of its graduates on the average in research or teaching.

(e) If a program operating under option A fails to place the required number of trainees in research or teaching, NIH shall reduce the number of trainees supported for the remainder of the award period. The grant will not be renewed if the average number of graduates entering research or teaching for the life of the award is less than a majority."

We believe implementation of this alternative will remove one important barrier to the pursuit of academic training by the young physician wishing to test his investigative wings in the research laboratory. It will clearly not solve the problem but we believe it will be helpful at little cost. This alternative also allows us to recognize that not all budding physician-investigators will turn out to be suitable for an academic career in medicine.

REMARKS BEFORE THE PANEL ON RESEARCH CAPABILITY
NATIONAL CONFERENCE ON HEALTH
RESEARCH PRINCIPLES
BETHESDA, MARYLAND

October 3, 1978

I am Susan R. Gortner, Associate Dean for Research, University of California, San Francisco, School of Nursing. I am pleased to be able to present the views of the American Nurses' Association Council of Nurse Researchers, of which I am a member and interim Chairperson of the Executive Committee, and the American Nurses Association Commission on Nursing Research, relative to planning principles in the area of research resources. My comments will be directed to the issues that we see in building an initial research base, in maintaining that base, and in consideration of strategies for sparing an increasingly scarce research dollar relative to multiple demands on its use.

First, and relative to building the base, the availability of federal program support to assist in the research development process has been a major factor in achievement of research capability. These institutional research development grant programs, offered by the Division of Nursing since 1966 and more recently by components of the NIH, have allowed institutions with limited resources who have a strong commitment to increase their research activities to compete for developmental funds. Without those funds, many of us suspect that it would have taken much longer to create the environments, equip the laboratories, negotiate for use of central resources, and bring on the faculty and investigative resources that are so essential to our research missions. They were critical for those institutions for whom the initial financing of a base for research was not generally possible through faculty fees, gifts and endowment, and here I refer specifically, among academic health professional schools, to nursing, dentistry, and pharmacy. We worry that the need for continuation of institutional research development funds may not be fully understood.

The second issue deals with the components of the developmental process. These are creation of the environment, that is the mix of human and physical resources, the proportion of investigators to clinicians, administrators, students; the physical and financial resources for research, and the time available, given the competing missions of the institution. We have found in academic nursing that a favorable climate for research is best developed through increased recruitment of research-oriented and prepared faculty and attraction of inquisitive students. Administrative support for research must be strong and sympathetic because our faculty resources are not ample. But this is not sufficient. Physical facilities and supporting clerical and technical services must be available in order to undertake research activities. The competing obligations of teaching, research, public service, and clinical practices require a continual reassessment of time and resources in order to reach a proper balance. Accordingly, the multipurpose institutions, among them universities and teaching hospitals, do not build their research capabilities overnight, and frequently reach the height of their activities only after a period of sustained development which may take a decade or more.

The third issue then becomes maintaining the base that has been built through public and private investment. Here we think it is helpful to consider the fragility and vulnerability of the creative process in science. There are lapses in ideas and in investigator productivity and, therefore, in research support through the individual project route. The availability of stable funding, either through a basic subsidy or through an award process that permits considerable institutuional latitude in the use of funds, will allow continuation of important scientific activities, provide support to young investigators to enable them to become competitive, and provide ongoing opportunities for precepting in the methods of science. Additionally, maintaining the base requires the maintenance, repair, and eventual replacement of research equipment and supplies. As our technology becomes increasingly sophisticated, so do our facilities become obsolete and even more costly.

In closing, we would like to propose several strategies for consideration by this panel in refining the principles relative to research resource development. First, we suggest that the public training and service dollar can contribute to institutional research facilities and resources if legislative authorizations and departmental policy permit. Notable here is the precedent set in the Social Security Act of 1936, in which authorization for maternal and child health services allowed a percentage of funds to be used for research and developmental activities. Notable also is the fact that most current health manpower training authorities (Titles VII and VIII) allow for the production but not the evaluation of practitioners and their programs, and therefore limit our knowledge regarding educational effectiveness. We have been constrained by our inability to examine practice sites and post-training competencies of nurse practitioners under the Title VIII legislation. The non-discretionary portion of the federal health and welfare dollar is growing and the discretionary portion shrinking, as we all know . If the training and service legislative authorities can be examined as to their appropriate and potential contributions to institutional research activities, there should result more opportunities for research that presently exist.

We would like to draw attention to the considerable need for research resources and staffing of nursing service departments in many of our large teaching hospitals. We would also like to suggest encouragement of collaborative and interdisciplinary efforts among scientists working in the intersectof biology and behavior, especially in non-categorical areas such as health behavior, self care, and management of pain. This growing field of scientific activity is known to some of us as the field of nursing research, to others as the field of behavioral medicine, but remains unknown, unfortunately, to many others because of scientific and professional preoccupations or prejudices.

Finally, we would continue to urge the well established process of peer review for institutional activities in research and for the development of evaluation procedures that may be more appropriate in the clinical and behavioral sciences and emerging fields, such as nursing research, than in the biomedical sciences. For example, to the traditional index of scientific publication might be added the appraisal of consumer or user groups relative to a particular clinical trial or health delivery strategy.

We have been pleased to have been able to speak briefly to the issues in the area of research capability and will be interested in the outcomes of your deliberations.

SRG:cw

RESEARCH CAPABILITIES IN CHRONOBIOLOGY AND IN RESEARCH ON DISEASES OF CIVILIZATION AND THE ENVIRONMENT

Erhard Haus, M.D., Ph.D.
Representing: The International Society of Chronobiology and
The International Society for Research on Diseases of Civilization and the Environment

Metabolizing structures, if studied as a function of time, invariably show cyclic variations of different frequencies ranging from milliseconds--like in nerve cells--to an entire life span of an individual or of a population. The ensemble of many of these rhythms which, in some frequency ranges, are held in phase by external synchronizers, manifests itself in the form of rhythmic variations of parameters of clinical interest like body temperature, blood pressure, heart rate, the cellular elements in circulating blood, numerous chemical parameters in blood, urine, saliva, etc.

During the last three decades, descriptive and analytical statistical methodology has become available to quantitate these biologic rhythms. Thus, rhythm parameters like frequency, amplitude and phase have become new endpoints in the definition of health. Optimal function of an organism--its "health"--is characterized by a sequence of reproducible and quantifiable rhythms in different frequency ranges including, e.g., ultradian (3-4 hours), circadian (about 24 hours), circaseptan (about 7 days), circatrigintan (about 30 days including the menstrual rhythm in the female) and circannual (about yearly) rhythms. Rhythm alteration may precede clinically manifest disease and, in some instances, may be implicated in the pathogenesis of disease.

The critical importance of, e.g., circadian rhythms for the susceptibility or the resistance of the mammalian organism has been amply documented for noxious stimuli like noise, bacterial endotoxins, radiation, ethanol, cardiac glycosides barbiturates, anesthetics and psychotropic drugs, etc. Circadian rhythms in susceptibility to agents used in the chemotherapy of malignant growth in animal experiments can make the difference between death of the host or death of the tumor from a given treatment.

The application of chronobiologic principles and techniques to animal experimentation and drug testing was regarded by the participants of a recent International Cancer Research Workshop as an essential part of good nonclinical laboratory practice. In view of the often dramatic differences in the effects and in the apparent "potency" of drugs given at different times, i.e., in different stages of the animal's circadian system, neglect of such principles in animal experimentation and drug testing leads to inaccurate--and often contradictory--results which may be confusing, costly and often grossly misleading.

In human health care, chronobiology has direct and practical application in:

(1) The definition of "normalcy" and of "usual values" of clinical and laboratory parameters.

Rhythmometric analysis of clinical and laboratory variables studied as a function of time allows to resolve the predictable periodic nonrandom variations (rhythms) hidden in the broad "normal range" obtained by random sampling over the entire period of a rhythm and to avoid the pitfalls of referring "normalcy" to samples drawn at a certain time (e.g., clock hour in the circadian range) usually chosen by its convenience to the investigator.

In functions with high amplitude rhythms, the same measured value may at a certain time be abnormally low, at other times be found within the "usual range," and at other times be elevated for this specific time.

(2) Recognition of time-dependent individual and group differences, indicating potential risk factors for disease and/or early (chrono-) pathology.

Rhythm alterations have been found to precede establishment of clinical hypertension in experimental animals and in man, and thus may be a key element in the early detection of circulatory and cardiovascular pathology. Chronobiologic sampling schedules, either by self measurement, automatic sampling or monitoring may lead to the early detection of pathology, which may manifest itself at one circadian system stage, but not in others. Such a situation can be found, e.g., in many patients with early hypertensive disease in all age groups where early detection may have a profound impact on preventive health care.

In geographic-epidemioloic studies, certain populations of women with low breast cancer rate (Japanese) show reproducible differences in serum prolactin limited to one certain stage, when compared to American women having a several times higher breast cancer rate. Host rhythm alterations were found in patients with malignant lymphoma, which may parallel those seen in experimental tumor systems in animals. Aging, as such, leads to certain rhythm alterations which may be characteristic for the aging process and which may open new avenues of prevention and treatment in gerentology.

(3) Rhythm monitoring as part of routine health checkups.

Single measurements of rhythmic clinical or laboratory parameters, without qualification for time as they are done today routinely in doctors' offices may be meaningless in many high amplitude rhythms. Sampling of such parameters under these conditions may be inconclusive or even misleading and, at best, is of very poor cost-effectiveness. The monitoring of well-defined circadian rhythms by noninvasive methods (e.g., body temperature) for several days prior to the visit in the office or laboratory would allow to sample at a defined circadian system stage (which is not adequately characterized by a given clock hour having a different meaning in subjects with different sleep-wakefulness schedule, different times of food uptake, etc.). Values obtained at a given biologic time of the individual (rather than clock hour) can then be evaluated against the background of time qualified reference values of the same individual or of a cohort of subjects comparable in age, sex, etc. Single sample spot checks may thus gain substantially in diagnostic value and become cost-effective.

(4) Study of the impact of environmental factors, social routines and work schedules on the human organism.

Crowding, air pollution, acute and chronic exposure to radiation are known to affect the time structure of experimental animals. On the other hand, the response of the organism to such stimuli varies as a function of circadian system stage. On the basis of the results of animal experiments and of some studies in man, it is expected that rhythm alterations may serve as an early gauge in the detection of environmental damage, and that the response to environmental hazards, allergens, etc., varies predictably as a function of time.

An ever-increasing segment of our population is exposed to unusual work schedules, shift work and phase-shift by translocation over time zones (intercontinental flights). Animal experiments have shown effects of repeated rhythm manipulations on health which vary with the experimental conditions, e.g., the age of the animals. Repeated phase shifts instituted in adult animals shortened the life span while in young animals, no such effect could be found. Adaptation to a phase shift of the dominant synchronizer(s) over several hours (e.g., time zones) in mammals, including man, occurs slowly over several transient cycles with the speed of adaptation varying from function to function. This leads to a state of external and internal desynchronization of usually synchronized circadian rhythms which may be accompanied by decrements in performance. Investigation in 5-day shift workers living on the usual diurnal routine over the weekend suggests that these subjects never really adapt to their altered work schedule, with the low of their circadian cycle in performance potentially occurring during their working hours. Increased accident rates and health problems have been reported.

Chronobiologic methodology in data acquisition and analysis will be essential for the documentation of the effects of shift work and unusual work schedules on human health and performance. After such information has been obtained, it may become feasible to detect by study of their phase-adaptation, those individuals who can and those who cannot adapt to shift work, and eliminate the workers who might suffer ill effects upon their health by such a schedule.

(5) Timing of treatment according to periodic changes in drug resorption, in the pharmacokinetics of drugs, and in the responsiveness and sensitivity or resistance of the patient to a therapeutic agent (chronotherapy).

The dramatic high amplitude circadian sensitivity-resistance cycles to many therapeutic agents obtained in animal experiments have shown that the mammalian organism as a circadian periodic system varies predictably in its handling of therapeutic agents and in its response to them. An increasing number of reports have now extended some of the findings to healthy human subjects and to patients. It appears that for many agents the "right" time of administration is of just as much importance as the right choice of agent or the right dosage (which may be circadian system stage dependent). The stereotype t.i.d. or q.i.d. dosage schedules should, for many medications, be a thing of the past.

Introduction of chronobiologic principles to clinical medicine and therapeutics is of importance in instances in which toxic agents have to be given in dosages which lead to damaging or even life-threatening side effects which often limit the treatment. This is especially the case in the treatment of cancer.

Experimental evidence suggests strongly that chronobiologic principles may be of value in the treatment of human malignancies. On the basis of animal experimentation, it appears justified to assume the timing of drug treatment in man may have an excellent chance of reducing toxicity for numerous chemotherapeutic agents. It is to be expected that a gain in tolerance can be achieved, presumably by administration of the drugs at a circadian system stage, when large populations of sensitive host cells in proliferating tissues are in a stage of the cell cycle not affected by the therapeutic agent being given.

The time of treatment, however, has to be chosen according to concomitantly studied reference rhythms. Since the relation of biologic timing and clock hour may vary from subject to subject, and circadian rhythms have been found to free-run or to show phase alterations after the exposure of individuals to certain chemotherapeutic agents or irradiation, the study of host rhythms which can serve as meaningful reference functions is an essential prerequisite for prolonged courses of chronotherapy. These reference or time marker rhythms have to be circadian periodic functions which can easily be monitored by noninvasive methods over a prolonged time span and at relatively low cost. Such variables may be body temperature, skin temperature over certain areas of the body (e.g., breast). Variables like sweat electrolytes and salivary functions may be useful and easy to measure by noninvasive and socially acceptable methodology, but no adequately miniaturized instrumentation with computer-compatible output is presently available to perform these measurements in a longitudinal fashion over a prolonged time span.

In patients undergoing chemo- or radiotherapy for malignancies, the maintenance of circadian periodicity also will have to be ascertained by the study of pertinent reference functions, and these functions will have to be followed during the course of treatment.

To optimize treatment, tumor marker rhythms should be sought wherever feasible, preferably by noninvasive techniques which can be used over a prolonged time span. Skin temperature above the tumor may be a pertinent reference function in some malignancies located close to the surface. Chemical markers like light chains, polyamines and others should be sought and explored for their possible relation to tumor metabolism and proliferation. If tumor rhythms can be established and followed, it should be attempted to optimally time treatment according to the time of maximum sensitivity of the tumor and relative resistance of the host. If this is not feasible, phase manipulation of host or tumor may be attempted. This represents a complex problem which will require rapid turnaround time of laboratory and of statistical analytical services, which are presently not available even at larger centers.

It appears that a critical amount of data has accumulated which shows the need for inclusion of chronobiologic concepts and methodology in chemo- and radiotherapy of malignant diseses. Some of the experimental results suggest that significant benefit could be derived from the application of chronobiologic principles, methodology and treatment schedules to clinical medicine, provided that the complex methodologic and logistic problems can be solved.

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In spite of its basic importance in physiology and pathology amply documented by animal experimentation, and in spite of the wide recognition of its potential importance for preventive and clinical medicine, chronobiology has thus far had little impact upon health care. The main reason for this is a grossly inadequate research capability in this field.

Although the importance of time in biology and medicine has been recognized since antiquity, modern chronobiology has developed only during the last three deacdes. Several factors have been instrumental in this development. First and foremost, the conceptual introduction of biostatistics into medical research, helped greatly by the advent of electronic computers, led to the development and wide application of statistical methods of quantitative rhythmometry. These methods allow the detection of rhythmic variations in the noisy time series of data encountered in physiology and medicine. Besides the detection of rhythms, the methods of inferential statistical rhythmometry also allow their quantitation with the determination of variance estimates for each rhythm parameter. The use of quantitative statistical methods also taught the investigators working in this field to appreciate the sampling requirements such as the number of subjects and measurement intervals needed to obtain statistically valid results in groups of subjects (transverse approach), or the length of study span and sampling interval needed in a single subject (longitudinal approach). These studies were aided by the recognition of the need for standardization of experimental animals and of their housing conditions for chronobiologic research and by the availability of animal facilities which allow such standardization.

Automation in laboratory medicine allowed the processing of large numbers of samples of blood or urine at a moderate cost. Still, the application to human medicine faces formidable obstacles. Many blood parameters which show high amplitudes of circadian--and often of superimposed ultradian--rhythms can be quantitated reliably in a single subject over a single 24-hour span, if samples are taken at 20-minute intervals or even at 100-minute intervals. A single individual, however, seldom shows statistically significant rhythm detection (and quantitation) in samples obtained at 4-hour intervals over a single 24-hour span. Thus, the (clinically important) rhythm quantitation of circadian rhythms in blood or plasma in a single subject has sampling requirements which cannot easily be met other than in the setting of a research ward.

In patients hospitalized in a general hospital, the cost of keeping the patient long enough to establish a valid baseline for chronobiologic studies is prohibitively high, and interference by other diagnostic studies renders the value of such a baseline questionable. Studies of blood parameters are limited by the amount of blood required for frequent sampling and by the number of venipunctures or the duration of stay of an indwelling catheter acceptable to the patient and compatible with good medical care. Urine samples are easier to obtain, integrate high frequency variations in blood, but often present a collection problem, i.e., in regard to complete collection.

Self measurements of the rhythmic variations of certain body functions (authrhythmometry) has yielded valuable results in the hands of motivated and intelligent individuals. Autorhythmometry could serve as an inexpensive tool in preventive medicine if applied to blood pressure, for example, and if taught and practiced in high school. Together with body temperature measurements, spans of 10 dayd of measurement of blood pressure by autorhythmometry (4-6 times per day) could serve as a valuable adjunct to an occasional or yearly physical examination, and would allow spot-check blood sampling at defined circadian system stages. The general use of autorhythmometry, however, is dependent upon and probably limited by the motivation and capability of the subjects to provide frequent and accurate measurements of the body functions to be studied.

In order to overcome the obvious bottlenecks in the application of the often dramatic results of chronobiologic investigation obtained in the animal laboratory to health care, certain research capabilities will have to be developed:

(1) Formation of Chronobiology Centers

A number of chronobiology centers should be established, each in conjunction with the medical school and graduate school of a university, which should serve as training institutions for chronobiologists and for the teaching of chronobiology, its methods and its applications to interested physicians of other subspecialties, and to medical and graduate students.

The centers should provide laboratory facilities for animal studies which, in many areas (i.e., of chronotherapy), will have to serve as a guide for the human application. The animal facility should include isolation rooms or chambers with adequate environmental control, facilities for timed access to food and water and for automatic urine collection (metabolism cages), and facilities for telemetering of body functions (e.g., temperature, activity, ECG) with computer-compatible data storage.

The center should contain a clinical unit with several patient beds in rooms and supportive facilities suitable for synchronizer phase manipulation and for telemetering of several body functions.

The center should have the computer facilities for statistical rhythmometry and data display, interphased with the telemeters and other automated measuring devices.

The staff of the centers should consist of physicians and Ph.D.s trained in chronobiology, who serve as consultants in experimental and clinical design of chronobiologic investigation inside and outside the center, engage in research at the center, and are responsible for its teaching functions. Each center should have a certain number of positions for medical fellows and graduate students in medical chronobiology. Advanced degrees (Masters or Ph.D. in chronobiology) may be offered by the university involved.

These centers should be regional resource centers in medical chronobiology and should train individuals capable of effectively applying chronobiologic methods and principles to clinical medicine and health care in general. The availability of such specially-trained individuals is essential if costly mistakes are to be avoided (every "most favorable" time in a sensitivity-resistance cycle is matched by a "most unfavorable" one in which damage by a given noxious agent is most likely).

(2) Development of Instrumentation for Chronobiologic Monitoring

The application of chronobiology to health care would be greatly facilitated by the capability of monitoring one or several body functions by noninvasive techniques over a prolonged time span with an instrument which is socially acceptable and miniaturized to the point of not interfering with the patient's activities and which provides computer-compatible output. Such instrumentation may be within the reach of today's technology, e.g., for functions like body and skin temperature, heart rate (ECG), blood O_2 content and sweat electrolytes. Longitudinal measurements of these and other functions by automated monitoring equipment would have widest application ranging from the selection of rhythmometrically-defined blood drawing times for health checkups, to the determination of a subject's adaptation or lack of adaptation to work schedules and shift work, to the detection of early chronopathology in preventive medicine and to the determination of optimal drug treatment times and the determination of drug responses.

In view of this broad range of potential applications, it appears conceivable that in a number of years (or decades) automated noninvasive instrumentation for the rhythmometry of one or several body functions will have a position as prominent as the stethoscope today in patient examination, and may serve on an even wider basis in preventive health care. The wide potential application would make the funds spent in the development of such instrumentation well worthwhile.

A critical mass of data has accumulated over the last three decades which strongly indicates that substantial benefits could be obtained by the application of chronobiologic principles to preventive and clinical medicine. The areas of application are extremely broad and involve all aspects of health care including work hygiene, shift work, early detection of pathology and guidance of drug treatment. In the guidance of drug treatment with potentially toxic agents, e.g., in the chemotherapy of malignancies, a substantial improvement of toxic-therapeutic ratios could be expected with immediate benefit to the patient. Nevertheless, the field is at an impasse, due to the lack of research capabilities in trained personnel, and in advanced technology which would allow the effective application of the results obtained in the laboratory to clinical research and finally to patient care.

Due to the broad impact of chronobiology on numerous facets of health maintenance, and in recognition and treatment of disease, a relatively minor investment in the research capabilities in this field can be expected to lead to very substantial long-range benefits for a large percentage of our population.

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STATEMENT BY EDWIN H. LENNETTE, M.D., Ph.D., PRESIDENT, AMERICAN SOCIETY FOR MICROBIOLOGY, TO THE PANEL ON RESEARCH CAPABILITY, NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES, OCTOBER 2, 1978

I am Edwin Lennette, President of the American Society for Microbiology and Chief Emeritus, Biomedical Laboratories, California Department of Health Services. The American Society for Microbiology is composed of over 29,000 members who contribute to the applied fields of infectious diseases, clinical microbiology, industrial fermentation processes, ecological microbiology, and food technology, as well as to such fundamental areas as immunology, pathology, genetics, virology, and oncology. The Society would like to thank you for providing me with an opportunity to present our views on this very timely subject.

We strongly urge that our biomedical research capabilities be increased and stabilized in order to insure future health gains. We propose that a minimum 5 percent of the health budget be allocated annually to support basic biomedical research and research training and that this be reexamined annually and adjusted for dollar value fluctuations.

Part of this cost increase could be accomplished by critical examination of cost increases in health care delivery, in administration, and also in research in the basic sciences. For example, our feeling has been that overlapping jurisdiction between federal agencies has contributed greatly to the ineffectiveness of some programs and to increases in health costs. We favor strengthening the authority of the dirctorship of NIH and cite the division of authority of the National Cancer Institute as an example of unnecessary cost and burden.

TRAINING

For several years we have been hearing a great deal about the on-again, off-again support of basic research and of basic research scientists. The same spigot effect when practiced in the administration of training grants or of individual fellowships, both pre-doctoral and post-doctoral, ~~are~~ is equally harmful.

The continued success of our scientific efforts in this nation is dependent in large measure on the recruitment of bright young people. Unlike those in a career in medicine or law, the research scientist can anticipate only a modest salary and is required to obtain most of his or her support for research. In our experience, young people of the caliber sufficient to perform productively will not enter a field in which remuneration is markedly less than in other professions unless they are supplemented financially during their training. We therefore strongly urge the implementation of a stable research training program that will adequately fund both individual fellowships and training programs at both the pre-doctoral and post-doctoral levels. We disagree that the present level of support for research training is sufficient. We contend that current funds for research training are inadequate. This is particularly true in training in basic disciplinary areas. Obviously, interdisciplinary research should be encouraged and supported, but not at the expense of disciplinary project research. The former is only as sound as the latter is strong. This disastrous trend must be reversed if we are to ensure a manpower pool of newly trained, bright biomedical scientists to meet national health needs.

CLINICAL TRAINING

The lack of clinical scientists and educators is a formidable problem.

Efforts should be made to encourage the research training of persons with a medical background. One of the best ways of effecting technology transfer is to have people who are knowledgeable both in clinical application and in research training. Efforts should be made, however, to encourage not only basic research training of persons with medical backgrounds, but also clinical training for research trained scientists at the doctoral level. The largest deficiency in technology transfer is in losing this resource, hence the quality in our clinical departments is decreasing.

We recommend that a special fellowship program be initiated for people with M.D. degrees and clinical training who can benefit from experience in basic research. We recommend that such fellowships carry an attractive stipend.

In conclusion, we realize that there are major constraints in the federal budget; nevertheless, it is evident from past achievements that advances through research have markedly decreased the costs of health care delivery and promoted technological advances. Means must be found to develop an appropriate and constant level of support for research and research training in the biomedical sciences that is more consistent with national needs than past research efforts have demonstrated.

Thank you for allowing me this time to express the opinion of the American Society for Microbiology.

STATEMENT TO PANEL 4 : RESEARCH CAPABILITY

Robert G. Waggener, Ph.D. on behalf of American Association of Physicists in Medicine and The American College of Radiology

Mr. Chairman and Panel:

I represent the American Association of Physicists in Medicine and the American College of Radiology. These associations have a combined membership of 14,200. They are primarily concerned with the application of both ionizing and non-ionizing radiation to the diagnosis and treatment of disease. The use of modalities contained within these disciplines accounts for approximately 6% of the total health care budget in America. The primary concern to our associations is the fact that we are grossly underrepresented in the overall program at DHEW. A most common attitude in government circles is "let industry fund the research" and in industry the attitude is "let the government fund the research". The net result is that only those modalities offering an immediate economic return are exploited with many promising modalities which require a longer development left to an indifferent future.

Many extremely promising methods and modalities of diagnostic techniques with therapeutic potential are simply not explored. We suggest that in terms of overall benefit to the health of our country, an investment, however modest, in exploring and exploiting these known physical principles has a tremendous potential for payoff. We suggest an identifiable segment of HEW for exploiting and exploring physical techniques for diagnosis and treatment of disease processes be established.

At the present time, this process is everyone's responsibility and in reality no one's responsibility. We are on the threshhold of some very exciting breakthroughs in applying known physical principles to diagnosis and treatment of disease processes including; image intensification, nuclear magnetic resonance, microwaves, infrared, ultrasound and advanced applications of x-rays.

Specific recommendations which we believe have a high potential for payoff include:

1) establishment of small seed money grant mechanisms for investigating applications of physical principles to diagnosis and treatment;
2) establishment of support for young scientists including both physicians and basic researchers to investigate these principles. We recognize that any support in this area, however modest, in view of current financial restrictions, would provide a potentially high yield in terms of its overall impact on the health care system.

Thank you for this opportunity to appear.

Testimony of The American Psychological Association

Panel #4: Research Capability

National Conference on Health Research Principles

Presented by Dr. Stephen D. Nelson

The American Psychological Association is pleased to have the opportunity to comment on the Draft DHEW Health Research Principles. A sound and comprehensive health research policy is essential in planning and giving direction to the various health missions of the Department. The Department is especially to be commended for the open and consultative process of developing the Principles, particularly in soliciting and incorporating the comments of such a wide variety of concerned groups and organizations. Not only will the Principles be strengthened by the inclusion of multiple contributions and perspectives; but effective collaboration on other issues will be facilitated by encouraging a climate of increased openness and trust. We would hope that the Principles, once implemented, are not considered to be forever immutable, but rather will be considered a living document subject to adaptation or amendment, should experience warrant.

Other testimony being presented here reaffirms the essential contributions (both unique and supportive) of the behavioral sciences to a proper understanding of health and the actions and care needed to support it. We wish to emphasize our understanding that the Principles -- both in their entirety and in each supporting concept -- are intended by DHEW to apply equally to the behavioral sciences as to the biomedical sciences, and our support for the Principles and their implementation is predicated upon this understanding.

Research Capability, with which this panel is concerned, is basic to and undergirds the accomplishment of the first three foci of the Principles: (1) fundamental research, (2) clinical applications and health services research, and (3) health regulation and promotion. Our comments on this topic will be organized around the three sub-principles and their supporting concepts in the order they appear in the Draft Principles. For the panel's convenience, we will present the draft statement (identified by its page number in the Draft Principles, Attachment #2), followed by our comments, followed in turn by our recommended revisions, wherever appropriate. Recommended deletions will be bracketed, and recommended additions will be underlined.

Draft: "Human resources must be renewed and maintained.... It is essential to bring into the research community new investigators with new and innovative ideas and to provide them with support to capitalize on opportunities. This is necessary to train and maintain the next generation of researchers. Research careers must be kept competitive with other pursuits in order to attract and train outstanding individuals." (Page 15)

Comment: APA strongly supports this statement. There are continuing, and in some cases growing, personnel needs within the behavioral sciences in all three of the foci on the health research continuum: (1) fundamental research, (2) clinical applications and health services research, and (3) health regulation and promotion. Within the last category are included the increasingly important emphases of prevention and health education, as well as research on the most effective dissemination processes. In addition to these three foci, there are also pressing needs for personnel who can provide linkages between them, in order to capitalize on opportunities involving more than one of the foci. This role can sometimes be played by researchers (especially if they receive broad and sound training within their generic discipline), but sometimes must be played by appropriately trained research administrators or Federal personnel who are responsible for funding research and training programs.

Provision of adequate human resources for health research requires first the recruitment, then the training of potential researchers, and finally maintenance and support of those demonstrating the greatest skill and most productive ideas. With regard to making research careers competitive with other pursuits, a major means for doing this is Federal support for research training in the form of either research assistantships or, far more desirably, training fellowships. Science is not a very lucrative career financially, especially when compared to practice in various of the health fields. Bright and creative young minds are likely to turn to other careers if they must go into debt to obtain a research degree, given that postdoctoral remuneration cannot easily or quickly compensate for that debt. Young investigators are the lifeblood of any science, and in their training phase they are relatively inexpensive to support. Six to eight predoctoral students can be supported for less than $50,000 a year. Health research needs a renewed Federal commitment to support research training at both the predoctoral and the postdoctoral levels.

Recommended revision: Add to the draft the following: "A major means for accomplishing this is a renewed Federal commitment to support of research training at both the predoctoral and postdoctoral levels."

Draft: "Talented individuals should be encouraged to pursue research interests in the early stages of their scientific and medical careers." (Page 15)

Comment: (1) If the word "medical" in the above statement was intended to refer to practice as contrasted with research, it should be replaced with a more general phrase applicable to all relevant health professions. (2) Women and ethnic and cultural minorities are still seriously underrepresented in the health sciences, and programs to enhance their career commitment to health research would benefit all concerned. Although recrutiment of women and minorities to research careers must begin at the pre-baccalaureate level, DHEW can encourage greater participation by these groups in health research by means of training fellowships (both pre- and postdoctoral) and research support.

Recommended revisions: Change to read: "Talented individuals should be encouraged to pursue research interests in the early stages of their scientific and [~~medical~~] health service careers. Expanded opportunities for women and ethnic and cultural minorities should be provided in the form of both research training and research support."

Draft: "Recruitment of young researchers to areas of greatest national need and scientific promise must be encouraged." (Page 15)

Comment: Again, the major mechanisms for encouraging recruitment into such areas are (1) research training support with greater numbers of awards going to the targeted areas, and (2) stable support for research in those areas. We hasten to add two crucial caveats to the former mechanism: (a) Although greater numbers of awards may go to targeted areas, other areas with more stable personnel needs should not be sacrificed to accomplish this. All areas should continue to receive appropriate training support. (b) Awards for targeted areas should carry with them the requirement that the recipients will have a thorough grounding in the broad knowledge of their generic disciplines.

Increased need for behavioral science research skills can be expected in several different areas. In their 1977 report, the National Research Council's Committee on a Study of National Needs for Biomedical and Behavioral Research Personnel commented on the growing importance of health services research and the significant role of the behavioral sciences in that field. In addition, the growing demand for professional and public accountability, together with the belated realization that a great deal of public health and medical technology remains untested, is producing pressure for systematic evaluation of medical and health technology and health-related programs. We now have few trained evaluation researchers in this country, and only a handful of these are working in the health field. Consequently, additional trained evaluation researchers will be required. Psychologists and other behavioral scientists are in an excellent position to make a significant contribution in this area because of their sound methodological training in science and research.

In addition to the health-related programs and issues already requiring the research skills of behavioral scientists, the probable introduction of a national health insurance program will make unprecedented demands upon the behavioral sciences for highly skilled researchers. Systematic evaluation to develop and discover the most effective and efficient health care delivery programs will be essential if high quality health care is to be available to all citizens at an affordable price. The probable need for skilled researchers in such areas cannot be met by current levels of production of research personnel in the behavioral sciences.

In countless other areas related to health--population and fertility behavior, occupational safety, nutritional behavior, behavioral components of physical health, strategies for prevention and behavioral components associated with it, and technology assessments and social impact assessments of health programs and technologies, to name just a few--the need for behavioral researchers can confidently be expected to increase.

Finally, we would suggest that in determining "areas of greatest need", improved methods for estimating manpower supply and demand be developed and used. A serious shortcoming of the NRC Committee's analysis of demand for behavioral scientists was that they considered only the academic sector, whereas in fact behavioral scientists are increasingly doing health-related research in nonacademic settings. The Committee's method caused them to underestimate the actual demand for behavioral scientists and thus to make inappropriately low recommendations for research training support for the behavioral sciences. Elsewhere in their 1977 report the Committee recognized their oversight and declared their intention to examine the nonacademic sector in subsequent reports.

Proposed addition: We recommend the insertion of a separate supporting concept, to be inserted between the one at the bottom of page 15 and the one at the top of page 16, to read as follows: "Quality standards for researchers should be maintained or strengthened in all fields, with special attention given to those undergoing expansion."

Draft: "Attention should be given to providing opportunities for promising clinically-trained individuals with demonstrated aptitude for research to develop into independent investigators as well as for Ph.D.s to enter clinical and other research disciplines." (Page 16)

Comment: In principle, we approve of the productive combining of research and practice skills, and point out that one of psychology's most prominent subfields, clinical psychology, has explicitly operated on this model for several decades, to the benefit of its effectiveness and creativity. In fact, the combination of research and practice skills virtually defines the Ph.D. in this field, and we are pleased that other fields are now recognizing its advantages.

However, because of its dual nature, clinical psychology has also had considerable difficulty in qualifying its programs and trainees for training support, due to an unnecessarily and inappropriately sharp line being drawn administratively between research and practice. If the above draft statement is to reflect a DHEW policy favoring overlap between research and practice, then we would expect interpretations such as those which have compromised clinical psychology to cease.

Draft: "It is essential to provide opportunities to individuals who have just obtained health professional or research degrees to embark on academic and/or Federal research careers." (Page 16)

Comment: We strongly support this statement. With college and university faculties becoming heavily tenured, and with increased competition for a diminishing pool of research funds, young researchers are often placed in great jeopardy regarding their long-term ability to successfully pursue a research career. Opportuntities must be provided for them to test their worth against somewhat fairer odds. We would suggest that a succession of postdoctoral awards is not an answer to this problem, since it merely creates a holding pool and postpones but does not solve the career problems of the young researcher.

Draft: "Programs aimed at the continuing education of health care practitioners must be encouraged so that new techniques, diagnostic tools, treatments and preventive measures which are the fruits of research can be passed on to the public through better medical care." (Page 16)

Comment: (1) The word "medical" in the last phrase is not sufficiently general to apply to all relevant health professions, and we urge its replacement. (2) APA supports the emphasis on continuing education, and has for some time been developing continuing education programs tailored to the needs of psychologists. However, along with the recognition of the necessity for continuing education must go the recognition of the necessity for its evaluation. Evidence is needed regarding its effectiveness in accomplishing its goals. Past experience in other professions is not uniformly encouraging that certain methods of continuing education are reliably effective. Evaluation is needed regarding such issues as: What methods or formats of CE are most effective? In what settings? Under what auspices? What quality control mechanisms are most effective?

Recommended revision: The last phrase should be changed to read: "... passed on to the public through better [~~medical~~] health care."

Draft: "Programs to support multidisciplinary, collaborative research approaches must be available." (Page 16)

Comment: (1) A distinction has developed in recent years betwen the term "multidisciplinary" (referring to persons from several disciplines working in parallel but with their efforts not being truly integrated in any significant way), and "interdisciplinary" (referring to truly collaborative efforts between persons of different disciplines where their respective approaches are meaningfully merged and integrated into a coherent framework). We would prefer the latter, and assume that this was the intended meaning.

(2) In addition to research support for interdisciplinary efforts, we believe that there must also be training opportunities in interdisciplinary approaches and methods.

Recommended revision: "Programs to support interdisciplinary, collaborative research approaches and training opportunities must be available."

Draft: "Major research activity at research and academic institutions such as health professional schools, graduate schools and Federal and National laboratories must be fostered, and research support provided in a stable manner. Performance of research is inseparable from the learning process, enriching both directly and indirectly the quality of health care.... Investigators and institutions need some measure of stability and should be buffered against radical short-term changes in policy." (Page 17)

Comment: The Draft Principles place great emphasis on stability in the levels of research support, and numerous groups have echoed this concern. We too share this concern and strongly support the principles dealing with it. However, quite apart from problems of instability of research support -- which we share with other disciplines --, the behavioral sciences have a more basic problem: that of the absolute level of research support. Across the spectrum of health-related research, the behavioral sciences receive only a small fraction of the research support received by the biomedical sciences. Federal support for behavioral science research in most areas does not measure up to the government's and the public's declared interest in untangling the many problems of health, both specific disorders and the delivery of services. In general, in both physical and mental health research, the closer an area of the behavioral sciences is to the biological sciences, the more likely it is to be well-funded by the NIH-ADAMHA institutes; and conversely, the farther such an area is from the biological sciences, the more likely it is to be seriously underfunded. The effect of this pattern is implicitly to deny in practice the validity of the unique contributions of behavioral science to health research. Such underfunding also perpetuates the self-fulfilling prophecy, pronounced by some, that the behavioral sciences have little to contribute.

In many areas the behavioral sciences have already demonstrated that they have their own unique and significant contributions to make, many of which are quite distinct from those of the biologically-based sciences. They too deserve the support necessary to more fully realize their potential. To the extent that such areas are underfunded relative to the objective need for their input, the public and the rest of the health research community must forego the contributions that only these areas can make. Further, because training in research is inseparable from the actual performance of research, opportunities for sharpening the skills of many of tomorrow's health researchers will be lost.

Recommended revision: Insert between the second and third sentences the following: "Research support for particular areas and topics should be commensurate with the national need for it."

Draft: "It is essential to provide an adequate level of long-term support to assure stability of training programs concerned with fundamental and clinical research in biomedical and behavioral disciplines." (Page 17)

Comment: (1) We believe that this statement should be extended to include health services research as well. The case for strengthening training support in this area was made quite well in the National Research Council Committee's 1977 report, and we need not repeat it here. (2) We repeat our position that both predoctoral and postdoctoral research training support are essential. Postdoctoral support is less well established in the behavioral than in the biomedical sciences, but it is increasingly seen as not only useful but indeed essential for particular areas or purposes. However, because the relative recency of postdoctoral support has not yet allowed the institutional capability for providing widespread effective postdoctoral training to be established, we do not favor a headlong rush toward emphasis on postdoctoral support.

We do favor increased postdoctoral support for behavioral scientists, but we do not favor it at the expense of predoctoral support, as has been recommended by the NRC Committee. Predoctoral support plays an absolutely essential role in recruitment and training of behavioral scientists, and the behavioral sciences have established highly successful training programs around this mechanism. We regard the severe reductions in predoctoral support recommended by the NRC Committee as fundamentally mistaken and extremely serious in their consequences, based as they are upon incomplete estimates of the demand for behavioral scientists.

We believe that this raises a broad policy issue, of which psychology is only the most visible example. It is this: to the extent that various fields or disciplines are moving into health research areas outside of traditional academic settings, then by making recommendations for reduced production of Ph.D.'s based solely on analysis of the academic sector alone, one is potentially undercutting the overall national capacity for performing this needed research. Further, the effects of such actions are likely to be felt for several years and are not easily or quickly ameliorated. Rather than attempting to slowly phase out predoctoral training support, the Federal government should reaffirm its commitment to it in health-related research, and encourage the creation and development of innovative predoctoral training programs appropriate to fulfilling the needs for health research in all institutional settings.

(3) Beyond merely providing sufficient numbers of talented people, health research policy must be fashioned so that those persons have the training and experience appropriate to performing their own role effectively. Increasingly, for efficient use of resources and to capitalize on opportunities for both research and application, it is necessary that health research personnel -- although specializing in a particular area -- be continually familiar with developments in other specialities and in other foci of the health research continuum. This includes:

(a) Solid, broad-based training in one's generic discipline, prior to training in more specialized areas;

(b) Familiarity and preferably experience with all three foci of the health research continuum (fundamental research, applied research and health services research, and health regulation and promotion); and

(c) Familiarity with issues of national health policy and science policy.

These requirements enable the person's own specialized work to be more coherently articulated with other aspects of the health research continuum.

Recommended revisions: We recommend the statement read as follows:

"It is essential to provide an adequate level of long-term support to assure stability of training programs concerned with fundamental, applied, and health services research in biomedical and behavioral disciplines. Federal support for research training at both the predoctoral and postdoctoral stages is essential, and should be provided at sufficient levels to ensure adequate research personnel in all components of the health research community. Quality standards for research training programs should be maintained or strengthened in all fields, with special attention given to those undergoing expansion."

Draft: "Physical resources must be renewed and maintained. This requires giving attention to both equipment and facilities.... A continuous assessment of ongoing needs and resources should be pursued." (Pages 17-18)

Comment: We strongly endorse this principle, because it pertains to behavioral research as well as to biomedical research. Many people do not think of the behavioral sciences as being heavy users of research equipment, but in fact they are. Many of the major subfields of psychology are as equipment-intensive as are the biomedical sciences. And like their colleagues in the latter group, psychologists are continually in need of more sophisticated equipment. However, since both state governments and Federal agencies have been cutting equipment items out of proposal budgets, behavioral scientists are often left with obsolescent and inadequate tools for conducting their research. We strongly urge the Federal government to commit itself to upgrading the physical resources of the health research community.

October, 1978

STATEMENT TO THE NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

MADE BY: Elliot D. Weitzman, M.D.
Vice-President, Association of Sleep Disorders Center.
Coordinating Secretary, Association for the Psychophysiological Study of Sleep.
Professor and Chairman of Neurology, Albert Einstein College of Medicine, Montefiore Hospital and Medical Center, Bronx, N.Y.

Since the time available is limited and others I am sure will have addressed themselves to the need of expanding research resources in the basic and applied investigating areas, I wish to focus my remarks to the critical resource needs of the important interface between fundamental research and the transfer and application of new knowledge to patient care needs in general but specifically to Sleep Disorder needs. Although much "lip service" has been given to the needs in this area, from the perspective of those of us at that interface, a focused, funded program to facilitate that interchange has been woefully lacking. Clearly, the most important resource is the infusion of a highly committed, creative, well trained group of scientists-clinicians. Unfortunately programmatic support has in fact decreased in this area forcing the enthusiastic young budding clinician-scientist to choose an independent private practice career or to be overwhelmed by higher priority hospital and daily patient care needs. Since the only reliable source of salary support comes from hospital, clinic and third-party insurance, the appropriate demands of administrators of these programs have the highest priority.

The second area of critical resource needs is the support of specialized patient care programs which will devote themselves to focused research application of new promising diagnostic and treatment modalities. These specialized Clinical Research and Treatment centers should be established within large medical centers which have the full panoply of academic support of a University-Medical School program. The present demand that all funding for such diagnostic and treatment programs be already proven non-experimental is clearly self-defeating and will continue to prevent initiation and experimentation of new approaches to specific clinical problems. The establishment of such centers will encourage healthy challenges to outworn nosologies, focus epidemiological studies and provide a well studied and defined patient group for future studies. If these are intimately coupled with basic research and education programs, the free exchange of ideas and individuals will be greatly facilitated. Finally, if such centers are approved, matching funds for new or renovated construction should be available to encourage institutions to commit space and equipment resources to such designated centers.

As many of you know, there have been major advances in our understanding of the basic mechanism of sleep, sleep-waking biological rhythm processes, the recognition of new clinical entities and the elucidation of well known clinical problems.

At the present time a growing number of sleep disorder centers are being established with the express aim of applying our scientific knowledge of sleep to the major clinical problem of abnormalities of sleep and the sleep-wake cycle. At present there are approximately 12 such centers in the United States. A national Association of Sleep Disorder Centers has been established with the express aims of encouraging the development of such centers, fostering basic and clinical research in the area, and ensuring, through an accreditation policy, high standards and responsible clinical functions of the established centers. Although these centers have only been in existence for A FEW years, it is abundantly clear that the range of clinical problems and numbers of patients seeking their services are very large. The four major categories of sleep disorders at these centers are: Insomnia, Narcolepsy-Cateplexy Syndrome, The Hypersomnia-Sleep Apnea Syndrome, and the Circadian Phase Shift Dysomnias. In addition, the following is only a partial list of clinical entities seen in a typical sleep disorder center: nocturnal seizures, nocturnal myoclonus, somnambulism, night terror attacks, nocturnal enuresis, bruxism, hypnotic drug dependency, nocturnal hallucinosis, and sleep-wake dysfunction of the aged. Although the development of an appropriate nosology of the sleep disorders has been sponsored by the Association of the Sleep Disorder Centers, clearly during the next 10 years we will see an increasing necessity for new definitions, revisions, and conceptual challenges to our present classification system. In this context some of the most exciting and valuable basic and clinical research will be done. It is therefore anticipated that [redacted] important research opportunities will be available in the field of sleep disorders to be applied directly to patient care problems. We hope that the National Institutes of Health will assist in providing both conceptual and substantive support for the interface between new scientific knowledge and its clinical application.

American Board of Clinical Chemistry
Represented by:

Professor Martin Rubin

Professor of Biochemistry,
Georgetown University
Director of Clinical Chemistry,
Georgetown University Hospital

An unbridged gap exists between the cultivated ordered academic grooves of basic science on the one hand and the consuming, hungry and increasingly expensive health care system on the other. In this country, the separation between basic science and clinical function is both figurative and actual. They are not only distinct in organization and administration, but are invariably separated in physical location. It should not be surprising that the consequent lack of communication and mutual misconceptions should have produced an uncharted, uncertain middle ground where pathways are indistinct and missteps costly. We expensively misuse technology on the one hand and neglect potential benefits on the other (1). Let me present a few illustrative examples to illustrate these points: with these, while recognizing the complexity and magnitude of the problem, allow me to present positive suggestions for your consideration and recommendation.

The Sometime Fallacy of "More is Better"-

Superficial consideration suggested that if the cost were the same it would be an advantage to provide many test results for the same patient specimen rather than just a requested few. Presumably, the reasoning went, the increased information would allow the physician to reach an earlier diagnosis and a more rapid initiation of therapy of the hospitalized patient. In addition, health maintenance would be facilitated since regular monitoring of many parameters would provide early identification of trends toward abnormality. Rising to this challenge, the genius of this nation's industry has provided complex, massive automated computer controlled instrumentation which can provide the results of twenty tests on a patient specimen at the same cost as perhaps two or three by more discreet processes. The outcome of this continuing and now popular trend was predictable on theoretical grounds and confirmed in carefully controlled prospective studies (1). Theory predicted that because of the broad range of normal individual variability and the non-specificity of most present diagnostic tests, there would be a large number of "positive" abnormal findings for the individual patient, increasing with the number of tests. An additional complication results from the design requirement that multitest instruments utilize a minimal number of different detectors for the final analytical measurement. Thus non-optimal analytical methods have been used for quantitation of the constituents of the most complex mixture known- the human-specimen.

The result is an increased level of imprecision and inaccuracy and a dilemma for the physician. Should the "abnormal" findings be further investigated? Additional testing is performed and the patient stay in the hospital is extended. There is truly a "High Cost of Low Cost Laboratory Testing" (1). Nonetheless, new administrative laboratory cost guidelines based upon the presumed lower unit cost of multitest laboratory testing will result in an increased overall hospital cost for the patient.

But Sometimes "More is Better";

In recent years, research support for basic science has provided for the development of the exquisite technology of gas chromatography coupled with various modifications of mass spectrometry. Most major basic science centers in this country have this equipment which can establish the chemical identity and molecular structure of the class of compounds which includes almost all drugs and poisons. Yet only one modest installation in this country provides this capability as a regional around the clock service function in support of diagnosis and therapy. Simpler procedures often fail to identify drugs in the suspected overdose problem of the comatose patient presenting at the emergency room. In such circumstances, the physician has no recourse but to rely upon the providion of life supporting assistance rather than the specific therapy that could have been available with more information. We have not translated advances in fundamental knowledge and technology into life and cost saving patient care.

And what of the future? Can we expect that significant new advances in basic research will become rapidly and widely available? A few days ago, it was announced that the assay of a serum isoenzyme of galactosyl transferase could serve as a possible marker of presymptomatic, preclinical development of subsequent cancer (2). The assay procedure is not a difficult one. It is, however, not likely to be readily and rapidly available in the clinical laboratory. A few of the reasons will be evident from the subsequent discussion.

Research Capability in the Clinical Laboratory;

The clinical laboratory is the crossroad where basic science can meet clinical problems and clinical needs. Today it is has neither the research capability nor the research manpower to respond to these challenges. Instead of providing the integrated interdisciplinary research focus to delve into problems of health and disease it has evolved into an expensive shopping center to fill orders for items that are neither necessary nor useful.

This is our present situation because we have not previously recognized in our educational system that neither a doctorate in science nor in medicine provides the essential combination of research capability and clinical knowledge required for adequate function in clinical laboratory specialities. Federal administrative guidelines- properly- would not allow me to offer employment in the clinical laboratory to the host of bright young scientifically competent Ph.D. biochemists who have been pouring out of basic science training programs in recent years. They have had no exposure in education or training to the exacting and responsible task of handling patients samples in the clinical environment. On the other hand, the graduates in medicine while trained in clinical science are deficient in their research capability.

A Modest Recommendation;

With a year of education and training in a suitable Board (1) approved University centered clinical laboratory, a talented Ph.D. biochemist would have attained sufficient background to qualify for employment in a clinical chemistry laboratory. With an additional year of employment the individual would be eligible for Board examination. An influx of such persons into the interface of science and medicine will have a profound catalytic effect. We could expect that their scientific research background and new clinical horizons would stimulate their creative thinking and lead to establishment of new research programs. Innovative programs by competent creative investigators would have no difficulty in competitively commanding the research support needed for research capability.

Implementing a manpower program to provide one year of support to twenty young scientists, 1 year to attain the above objectives would not be difficult or expensive. The reallocation of $400,000/year of manpower funding could rapidly return major benefits in decreasing the cost and improving the benefits in the application of new knowledge fo the problems of health care.

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1. E. Benson and M. Rubin, "The Logic and Economics of Clinical Laboratory Use", Elsevier Medical Publishing Co., New York, 1978.

2. Weiser, M. M., Podolsky, D. K. and Isselbacher, K. J., "Cancer Associated Isoenzyme of Serum Galactosyl-transferase". Proc. Nat. Acad. Sci., 73, 1319 (1976).

3. Martin Tubin and Per Lous, "Education and Training for Clinical Chemistry" M T P Press Limited, Lancaster, England, 1977

Presented by Michael Gordon, Ph.D.

for

The Society of Teachers of Family Medicine
and

North American Primary Care Research Group

The Society of Teachers of Family Medicine is comprised of approximately 1,440 members, all involved in family medicine education and training programs. It is an interdisciplinary society with members representing medicine, social work, education, pharmacy, administration, nursing, the behavioral and social sciences, and other fields. Our members pursue their professional activities in medical schools, community hospital teaching programs, and in a great variety of community-based teaching practices. In the spring of 1978 the Research Committee of the Society was charged to review and articulate principles and strategies which might profitably govern the research efforts of those in our discipline. That work began during the past summer and was accelerated in response to Secretary Califano's request for input into the development of a federal strategy for supporting health research. The document presented here has been prepared by a task force of the Society and will be submitted to the organization's board of directors at its next meeting in October, 1978. Many of the members who are involved in research also participate in the North American Primary Care Research Group. This testimony is a joint effort of these two organizations.

FOCUS 4: RESEARCH CAPABILITY

Responsibility for insuring that the nation's health research capability is maintained at a high and productive level must be shared between the federal government and the multiple research institutions in our country. The collaboration, interchange of ideas, and sharing of results necessary for the accomplishment of research gains know no state boundaries. This must be a national priority and therefore deserves support on the federal level. We would address here primarily the need for the human resources involved in maintaining that research capability. We would urge that the federal government continue and expand support for training research personnel.

In another portion of this document (unifying conepts), we have referred to the need for joining together in research efforts individuals from a variety of scientific disciplines. We have also stressed the need to provide cross training for individuals from one discipline who must bridge the gap to another in their research efforts. For example, we see great need for training of clinicians who understand and use the scientific methods of the social and behavioral scientists. Past research advances have demonstrated the wisdom of similarly combining clinical and basic biomedical training. Conversely, we would think it important for those trained and educated in non-clinical sciences to become immersed in the work of clinicians and their environment.

Training, as envisioned here, takes a long period of time. We would urge that the federal effort therefore provide for lengthy career development awards and/or fellowship awards of at least five years in duration. The mechanisms for supporting such training may be quite varied. However, we would reaffirm the desirability of providing institutional support to universities or research centers for mounting such research training programs. This makes it possible for those institutions to select candidates matched to the strength of the institution. It makes available the "seed" money necessary to support the initial investigations of research trainees. It provides an accountability which would be difficult to maintain directly from the federal level to research trainees. Other approaches for support of research training should certainly be explored, but this tried and proven method should be maintained and strengthened.

In connection with enhancing research capabilities, we would urge that research training programs remain as broadly based as possible. The individuals trained in them should be able to move easily from one area of health research to another as the questions facing them dictate. The temptation to focus on specific categorical diseases is great. We would urge caution so as to avoid unnecessarily narrow research capability among those trained in targeted programs.

The cost of research training and medical research is an inseparable part of the total of health care costs. It should be recognized as such in any future financing plan. Just as the depreciation of hospital and clinic buildings, payment for the services of nurses and doctors, and payment for medicines and diagnostic equipment, the cost of training future researchers must be covered in the total funds allocated to health care.

In summary:

1. Our health research capability is a national resource. Training of future researchers should be supported at the federal level.

2. The cost of maintaining this research capability is part and parcel of the total health care package. Future financing plans must allow sufficient funds for research training and resources.

3. Appropriate research capability demands that future researchers be trained to bridge among the clinical, biological, social and behavioral sciences.

4. Research training is a lengthy process requiring support of promising trainees for periods of at least five years.

THE LIVING BANK Berniece Burkhardt, Controller
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RESEARCH CAPABILITIES

October 3-4, 1978

The following position paper of The Living Bank is submitted as part of the HEW Conference on multi-year strategy for support for health research:

1. PURPOSE

The Living Bank is a non-profit service organization dedicated to helping those persons who, after death, wish to donate a part or all parts of their bodies for the purposes of transplantation, therapy, medical research, or anatomical studies. It was chartered as a Texas corporation August 9, 1968.

2. ACTIVITIES

A. Education

In an effort to educate the public that being a donor should be the usual rather than the unusual thing, The Living Bank fulfills public speaking engagements before religious, civic and community groups and assists in courses on death and dying. Publicity, both local and national, through newspapers, magazines, radio and television, generates thousands of inquiries each year.

B. Registration

The Living Bank has responded to more than 600,000 telephone and mail requests for information. When such a request is received, a brochure is sent explaining the donor program, together with a donor form and a donor card. The inquirer may then complete the legal documents and return the donor form for processing and registration.

C. Referral

The Living Bank maintains a 24-hour telephone referral service in order to make timely referral of donations to medical schools, eye banks, kidney transplant facilities and other organ banks in every state of the union. There is only a limited time following the death of a donor in which to harvest the organs, i.e.:

vital organs (kidneys, hearts, lungs) -- 20 minutes
corneas -- 4 hours
skin -- 18 hours

It is therefore necessary for prompt referral that a current directory of telephone numbers, institutional procedures, and names of personnel for all appropriate medical facilities be maintained. Our records reveal that 91.5% of organ and body donations of members of The Living Bank are utilized, primarily due to our 24-hour referral capability. The remaining 8.5% are rejected for medical reasons.

3. JUSTIFICATION OF NEED

Our country has some of the most outstanding medical centers in the world, where life-saving kidney transplants are being performed; corneal transplants are bringing sight to many blind persons, and other organ and tissue transplants are aiding in the treatment of the severely burned, bone cancer, deaf ... the list is endless! THE SHOCKING FACT IS, HOWEVER, THAT MANY OF THESE TRANSPLANT AND RESEARCH PROGRAMS ARE SEVERELY HANDICAPPED BY THE SHORTAGE OF ORGAN AND BODY DONATIONS.

An essential resource to medical research is a sufficient supply of human materials to enable present transplant or tissue utilization programs to continue, as well as to serve the breakthroughs on the horizon which will bring hope to many persons suffering from diabetis, cancer, and the like.

4. FACTS CONCERNING PRESENT ORGAN DONATION PROGRAMS

A. The American Medical Association issues uniform anatomical gift cards. Most medical schools have their own willed body programs. Organ donor programs, in conjunction with the issuance of driver's licenses, exist in most states.

B. Specific groups provide educational information concerning their particular program (i.e., kidney foundations, eye banks, The Deafness Research Foundation, skin transplant centers, The National Pituitary Agency, etc.), and often this material includes a donor card for that program only.

C. The Living Bank is not a medical organization, but rather a humanitarian endeavor serving all programs in need of organ donations by referring the donor's gifts to the specific medical organizations for utilization.

D. Persons making the commitment to be a donor are a very special kind of people, with deep concern for others. Therefore, it is important that the offer of such a donation be handled sensitively at the time of death. It is pointless to educate people to be donors if their gifts are not utilized, or if it results in confusion and frustration for the grieving family in attempting to carry out the wishes of their loved one.

E. Much to our astonishment, we have discovered repeatedly that hospital and emergency services personnel (ambulance, police, etc.) lack adequate information for proper handling and timely referral of such donations.

5. RECOMMENDATIONS

A. Education must include not only the public, but those coming in contact with the donor so that proper handling and timely referral will enable the utilization of such donations. This includes hospital administration, nursing staff, physicians and surgeons, ambulance staff, police officers, firemen, paramedics, and other emergency service units, as well as morticians. This could partially be addressed through continuing education programs in hospitals and universities. The educational process should encompass the various medical groups requiring organ or body donations, and their specific requirements. It would require continual updating in order to keep current with medical research and advancements. Money needs to be allocated for this comprehensive education.

B. Registration. At the present time people carry many forms of donor cards. To our knowledge, 47 states have some form of organ donor program associated with their driver's licenses. The majority of the cards do not carry a 24-hour telephone number where assistance can be offered in making timely referral. An organ donor registry which contains appropriate data concerning all organ donors needs to be established and maintained. This could either operate at the state level or feed into one national registry. Funds need to be allocated for the research and methodology of establishing such a registry, and then the actual development of same. This would require advertising and promotion in order to reach all persons presently carrying some form of donor card. The data should then be fed into a computer system for purposes of recordation and retrieval. This would require a substantial investment in the beginning and continuing maintenance funds.

C. Referral. The registry referred to above should also contain current data on all programs requiring human material throughout the United States, including statement of need, handling instructions, carrier, and other pertinent information necessary for effective referral of donations at time of death. This would require constant update. An emergency WATS number should be assigned to this program.

D. It is essential that funding be made available to develop a comprehensive organ donor program to serve the medical research needs not only of today, but for the foreseeable future.

5. RECOMMENDATIONS (continued)

The Living Bank is uniquely qualified to research and develop such a program. This is borne out by several factors:

- It serves all groups and organizations, rather than being limited to only one area of medical concern.
- It is the most widely known and recognized program throughout the United States which encompasses both organ and body donor programs.
- It receives regular national attention via newspapers, magazines, television and radio.
- It has a current membership of approximately 100,000 card carrying donors, and new members are being added by the thousands each month.
- Its record of 91.5% utilization of referred donations attests to the successful operation of its program.

Organ and body donation is considered a "voluntary giving of oneself to others." There is no remuneration associated with such a gift. The only payment is in the satisfaction of knowing this gift has been offered during one's lifetime. Therefore, it is even more important that adequate programs be funded to allow this process to occur effectively and in an orderly and sensitive manner.

Submitted by:

Lorraine V. Gress
Executive Director

Date:

October 3, 1978

Presented by:

Berniece Burkhardt
Controller

for

Glen W. Karsten
President

Anne M. Briscoe, Ph.D. Page 1 of 2

October 3, 1978 Public Testimony

National Conference on Health Research Principles

PANEL 4 RESEARCH CAPABILITY

I am Dr. Anne Briscoe, Director of the Biochemistry Laboratory in the Department of Medicine of Columbia University at Harlem Hospital Center. Today, I am representing the American Association for the Advancement of Science officially, and unofficially speaking as the past president of the Association for Women in Science. I would like to thank the Panel for permitting me to participate.

First, I would like to add an enthusiastic endorsement of the views previously expressed that greater federal support of basic research is urgently needed on a long term basis, as well as an expansion of federal support for undergraduate, graduate and post-doctoral training, with specific plans for career development of minority persons and women.

Addressing the challenge stated by Secretary Califano to develop principles for a five year budget to permit the greatest scientific benefits fo the money spent, it is here suggested that we might:

1. Explore ways of reducing the cost of award and review of research grants.
2. Simplify the application procedures.
3. Review productivity in depth after say four years of a five year award rather than before. Stop requiring, in effect, that a large part of the data be collected before the initial site visit or review.
4. Reduce the number of large grants made to a few principal investigators since part of the mission of these becomes the need to perpetuate themselves.
5. Instead, increase the number of small and medium sized grants to a larger number of investigators especially at an early career stage.

6. Similarly, return to the system of the 1940's and 50's when N.I.H. fellowships were awarded directly to individuals who then selected the department and institution in which to study.
7. Set up a division to review applications separately from scientists at small undergraduate colleges. These part-time researchers have fulltime influence on the career choices of college students. Without research funds, these teachers become separated from the larger scientific community with resulting decrease in the quality of undergraduate education.
8. Set up a committee to act as a bridge with the private sector to devise a system of upgrading and cost-effective replacement of obsolete equipment. It is here that many research dollars are unintentionally wasted. Planning for better utilization of expensive equipment within institutions could be another function of the committee to avoid unnecessary duplication of expensive facilities.
9. Finally, establish a committee to study the problem of career stagnation of the Ph.D. scientist in clinical research. Many of these people are women employed in clinical departments and encounter the double-bind of being female and a Ph.D. in the M.D. domain. Opportunities for independent research are often lacking and science as a whole loses the benefit of their full potential.

Testimony Presented to the Panel
on Research Capability
Dr. Kirklyn Kerr
Assistant Dean for Research and Advanced Studies
Louisiana State University
School of Veterinary Medicine

National Conference on Health
Research Principles

October 3, 1978

Dr. Russell, Dr. Danforth, distinguished panel, I have come all the way from Louisiana because of my interest in what this group is talking about. I am Assistant Dean for Research and Advanced Studies at the new School of Veterinary Medicine, at Louisiana State University. I feel that the animal part of research capabilities needs to be addressed. I would like to point out just a few things quickly to this panel.

My own background, so that you can get this in perspective, is that I am a DVM, PhD, but part of my training was in a medical school in microbiology and pathology. I have just recently moved from Ohio State University to Louisiana to my new position. In Ohio I had worked as Director of the Division of Pathology in the School of Veterinary Medicine, and I worked closely with the medical school. We interacted on seminars, teaching, and case presentations, and I was a cooperator on numerous research projects with people in the School of Medicine. So that, in general, is the position I speak from.

We have very few people in research or going into comparative research because we do not have funding. Listening to other speakers made it apparent that that is a common problem. It depends on where our priorities are, and I think we must remember the importance of animal resources in research. I am biased, but I think that is a fact. I would like to speak about just a couple of things then.

If we do not train researchers in the area of comparative research, I think we are wasting a vast resource. I am speaking about the need for researchers; it adds additional responsiblities to those of us in academic institutions to train these people. As a research administrator, I must see that people are trained to produce food animals, just to solve the diet problem in the world and the country. But from a comparative medicine viewpoint, I think the health benefit is much more obvious of training people in that area.

In veterinary medicine right now, we are in a time where we are getting the top brains in the country, applying as students, and depending on the year, only about one in fourteen get in. Grade point average for an entering class averages 3.7. After these students graduate--obviously most of them go into practice--many of them go into practice or other areas because there are no funding opportunities for research. I think we are wasting a lot of the brains that we are graduating by teaching them--not that it is unimportant--to do surgical techniques and vaccinate small animals in the suburbs of the cities. I think that we need to use some of them for more valuable activities than that.

The main area we need researchers in is the area of comparative pathology. We are not graduating new comparative pathologists. A lot of people feel that you cannot interpret animal data and relate it to human data. I submit that we do not have enough people interpreting that data. We still have to use animals for a large part of our basic research, yet we are not training anyone in basic interpretation of lab animal data. We cannot hire a clinical pathologist in veterinary medicine; they are not available. When we do get one, we steal him from someone else, and industry may take him from us.

In laboratory animals, the costs are becoming prohibitive because of rules. You cannot afford to waste animal resources; you must have these people available. The rules on lab animals are making it prohibitive to even keep animals and to do the work, unless you have highly trained specialists on your research team.

Because of my training as a pathologist, I feel that the area of pathology and toxicology has had its own guidelines dictated by the public. The saccharin episode and some other problems that initiated the need to test every product that comes into human contact, to see if it is toxic or carcinogenic, before it can be put on the market. When these rules are placed on our industrial concerns, they have to hire people. They have literally taken everyone that we have in academia, by paying them double the salary that we can, and we are not training anyone else.

In the area of carcinogenesis which I work in, the need is tremendous to have the people trained, not just as task force teams, but as primary investigators in the animal resource area.

Veterinarians can service primary researchers on project teams, and I think that we can make great strides if we utilize this resource. Let me point out that Merrick's disease in chickens was shown to be a herpes virus years before Burkitt's lymphoma was shown to be one in man. NIH must speak to this need to get veterinarians into the research team.

In the 60's most veterinarians were trained on training grants, but that resource has since been dissolved. The people who are working in research areas are people off those training grants, and I helped train some of those people. Post-doctoral fellows are the only way that we now have of getting money to train a veterinarian in advanced studies in this category. When we apply for a post-doctoral fellowship, for example in cardiovascular disease for a DVM, the review committees do not always recognize the need, because they say, "That's a veterinarian, what's he going to contribute?" If you mention laboratory animals they can understand that, but they do not understand a veterinarian

NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

WITNESS: Dr. Brian A. Curtis PANEL: Research Capability

INSTITUTION: Associate Professor of Physiology
Peoria (Illinois) School of Medicine

ON BEHALF OF: Public Affairs Committee, Federation of American Societies
for Experimental Biology

The document mailed out by the Department as the basis for testimony at this Conference states that "The principles do not address organizational changes or specific program priority setting." On the other hand, the Secretary at the opening plenary session yesterday said that what he wanted most out of this exercise was a notion of our priorities and what he needed the least was a lot of belaboring of the obvious importance and need of research. I will try to play it safe and give you a little of each.

Those who ask why the federal government should be involved in the support of health research might ask as well why the federal government should be involved in the support of national defense.

The answer in both cases is the same. The health of the country, like the military security of the country, is a national goal shared by all and of benefit to all.

The problem with these two common goals is that each is beyond the means of any single segment of society to achieve. Each by its nature and the scale of resources required is beyond the capacity or incentive of private interests to address.

If these common goals are to be achieved it will be only through continuing national effort and national support.

At the risk of belaboring the parallel, it should be noted that research facilities and equipment, like military weapons systems, do wear out and do become obsolete. The difference is, obsolete military equipment is routinely replaced by a new generation of hardware. We are looking forward to the day when replacement rather than improvised repairs will be the order of the day in research laboratories. To offer a specific of the kind requested by the Secretary, it is suggested that as a matter of principle the government should open its eyes and deal directly and openly with the problem of deteriorating and obsolescing laboratories.

Let me now go from a specific on physical resources to a specific on human resources. In meeting the manifold personnel requirements of national security, the Defense Department operates the largest education and training establishment in the world. The sine qua non of research productivity is a critical mass of highly qualified and highly trained people. The vitality and viability of the research enterprise depends on a steady flow of the brightest and most imaginative young minds. The magnet to attract the best and the brightest is the National Research Service Awards program. This program serves a unique and very important national need that cannot be met in any other way by replenishing the ranks in this form of national service.

In spite of the self-evident need for this program to serve the common good, it has been under persistent attack from various quarters of government and has suffered from what Congressman Rogers has described as "uncertainties and disruptions under two previous administrations." To offer another specific of the kind requested by the Secretary, it is suggested that as a matter of principle the government should acknowledge the importance and reaffirm its support of biomedical and behavioral research training.

A final specific. Nothing is more central to our research capability than our ability to determine which research is worth doing. The mechanism for doing this is the two-tier NIH system of peer review. It is urgently recommended that additional study sections be chartered so that the system can provide adequate review and honor its public trust. It is also urgently recommended that the two-tier peer review system be extended to cover all mechanisms of research support, including center grants, program projects, contracts and NIH intramural programs.

Research Capability

Mr. Chairman, Panel Members, Ladies and gentlemen:

I am Edward G. High, Professor and Chairman, Department of Biochemistry and Nutrition, Meharry Medical College, a position I have held for the past eleven years. In addition I have served and continue to serve on a number of professional national advisory committees, councils, and boards concerned with health care, biomedical research, and related activities. For more than two decades, I have been actively involved in research and concerned with programs designed to increase the pool of scientists in biomedical research. In 1956, a Sigma Xi organization in Nashville, Tennessee, as a result of our efforts, developed a proposal designed to improve and to increase the pool of science trainees in high schools and colleges. Some of you will recall that after the launching of Sputnix I in 1957, much was said and written concerning the quality and quantity of science education programs in our schools. Steps were taken to make available to our youth wide opportunities for training in science and mathematics. Inspite of these increase efforts and gaines, the number of minority and women this affected and who entered into the sciences was pitifully small.

Although in the past five to ten years we have made commitments to increase the entry of minority groups into science as well as other professional activities, this commitment is far from being realized (fulfilled) and as a result it has left much to be desired. I think we all will agree that progress has been made, although slow and often frustrating, but the minority representation is far from being representative.

Let us look briefly at some statistics. According to Padulo (1) approximately 16% of the U.S. population is minority. Also a survey report of El-Khawas and Kinzer (2) of graduate schools, indicate that only 7.2% of all graduate students are minority. These data also indicate that only approximately 1.7% of graduate enrollment in the life sciences, mathematics, physical sciences and engineering are black inspite of the fact they constitute 11.1% of the total population and 4.4% of the total graduate enrollment. Although not quite as bleak, a similar corollary exist in other graduate education disciplines as well as in medicine and dentistry. What does this mean? It is obvious that minority groups and in particular blacks are grossly under represented in the biomedical sciences. (For further detail see attached Table taken from Melnick and Hamilton (3).

Although these figures represent a substantial gain in what the situation was a decade ago, it is extremely disturbing to recognize that there is evidence of a slowing down of these gains. If this trend is not reversed, this could negate much of the gains that have been made. After a century of inequities, one can not expect any population group to catch up after only a five to ten year affirmative action program. In fact, it is only now after the initiation of present programs that minority groups are beginning to move into the main stream of American and international science. Certainly, we all recognize the time factor involved in educating and training scientists from the early years through the professional years.

Several statements made in Secretary Califano's Initiative-Development of Health Research Planning Principles, should be re-emphasized at this point. "Over the past ten years, Federal support for basic research has declined by nineteen per cent in constant dollars; The quality of scientific plant and equipment at our great research institutions has badly deteriorated; Research opportunities for young university scientist have been declining-and so the percentage of young scientist on our faculties declined from 43 per cent in 1968 to 27 per cent in 1975, a chilling omen for future scientific achievement".

Certainly we must maintain a proper balance in Basic Biomedical Research for which NIH is internationally famous. The excellence that has existed in this area should not be compromised in either quantity or quality and certainly not the latter within limits of available resources. To accomplish this, it is obvious that the quality of plant and equipment material must be maintained and funds must be made available for additional equipment when needed to adequately carry out the proposed basic research.

Special emphasis should be put on young investigator awards and in particular awards to minority and women who, because of lesser advantages but with apparent outstanding potential, do not have the track record of more senior investigators at some other institutions. If we do not have a program to encourage these young scientists with special emphasis on minority and women, much that has been gained by present programs will have been lost. These people include a very important and significant sector of our human resources. To lose them would be tragic. We need to nurture these resources which will cause a continual development of a broad sector of our population in biomedical research.

As previously indicated, research manpower is critical in terms of minority and women. The special emphasis programs that have been developed to encourage and to bring more minority and women into biomedical sciences and research should be continued and increased in scope with new and immaginative programs. This should be a viable program with stable funds, not subject to be cut off each year or with change of administration. This will likewise add broader strength to our research manpower needs.

Finally, a program to achieve equality of minority groups and women in scientific and technical fields must be directed twoard increasing the pool of minority available for graduate school and health professional school enrollment.

This increase may be accomplished with a planning program involving a multidimensional approach or strategies. This is a top priority which needs developing within the NIH plan and with goals and objectives which can be obtained in a defined period of time. It seems that a subcommittee could work on the details of such a program. In fact, we should look very closely at the best way that this can be done.

I appreciate the opportunity to have the priviledge to present my point of views on this extremely important subject at this hearing.

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PRESENTER'S NAME: John A. Wacker
INSTITUTION AFFILIATION: Association for Children with Learning Disabilities
PANEL ADDRESSED: Research Capability

Parents of learning disabled children have historically been very willing to cooperate in research that could help their children. We estimate that in a major research effort at least 20,000 learning disabled children would be available for certain types of research.

United Action for Animals, Inc.
205 East 42nd Street
New York, N.Y. 10017

Presented by:
Eleanor E. Seiling, President

PANEL 4 - RESEARCH CAPABILITY

It is common knowledge that one area of critical deficiency in research capability is in the area of cancer research and testing. Why is it that a nation capable of landing a man on the moon continues to rely on cancer safety testing methods that were developed at the turn of the century? For example, the "Maximum Tolerated Dose," routinely used in cancer safety tests, was described in 1927 by a British researcher who pointed to its earlier use in 1910 (Proc. Royal Soc. of London, Series B, Vol. 101, 1927). Is this the best this country can do? We observe that, while the National Cancer Act of 1971 mandated the National Cancer Institute to "expand, intensify, and coordinate" cancer research, as far back as 1908 a British scientist drew up a "Draft of a Scheme for Enquiring into the Nature, Cause, Prevention, and Treatment of Cancer." (Cited in: Arch. Pathol. 2(5), November 19, 1926). The 1908 plan appears to be a more serious one than the National Cancer Act of 1971. Congress must be faulted for this, but so far as I can see the National Cancer Act of 1971 does not prevent the NCI from supporting innovative cancer testing and research.

It seems self-evident that the continued reliance on methods that were the fashion at the turn of the century and probably before severely restricts this country's cancer research capability and may readily account for the current public disenchantment with the lack of progress in cancer research and testing. There is an urgent need to modernize cancer research by using the vast number of valid non-animal research methods and providing incentive for the development of more. Let's face it: research on animals has gone about as far as it can go.

As one explanation of why so much cancer research and testing is routine, I note that veterinarians, trained in and devoted to animal research, hold policy-making positions in at least four federal agencies. A veterinarian holds the position of Associate Director for Carcinogenesis Testing Program at NCI. A veterinarian is in charge of the Priorities and Research Analysis Branch at the National Institute of Occupational Safety and Health. As of June 8, 1977, another veterinarian served as Acting Associate Director of the National Institute of Environmental Health Sciences' Research Resources Program. As reported in the Federal Register of April 6, 1978, a veterinarian is responsible for developing cancer testing standards at the Environmental Protection Agency.

Furthermore, during Congressional hearings, the directors of NCI and NIEHS can't seem to testify on their own concerning cancer but each must have a veterinarian at his side. (See: House Hearings on Cancer-Causing Chemicals, Part 1, Serial No. 95-91, 1978; and Hearings before the Senate Subcommittee on Health and Scientific Research, Oversight of Biomedical and Behavioral Research in the United States, 1977, Part 2).

Thus, we must ask: Is veterinary research the best this country has to offer in its war on cancer? At the very least, should not this nation's most highly educated and trained scientists be standing beside the directors of the executive agencies when they testify at Congressional hearings? Is this nation's cancer research capability to continue relying heavily on the talents of veterinarians?

The whole area of toxicity testing is in need of modernization. Although Congress requires that chemicals be tested for acute effects, which means the routine LD_{50}, one toxicologist has referred to this test as "a ritual mass execution of animals" (Progress in Toxicology, Special Topics, Vol. 1, Springer-Verlag, N.Y., 1973). Innovation in this area is stagnant. The acute tests (i.e. LD_{50}) were conducted years before the label itself was invented. In the early 1900's, British experimenters commonly performed tests to find the dose of a chemical required to kill half the test animals. Various names were proposed for this dose, such as "minimal lethal dose," "minimal effective dose," "fatal limiting dose," "median effective dose," etc. (J. Hygiene, Vol. 9, 1909). Researchers at Franklin Institute Research Laboratories, Philadelphia, have developed a statistical method for prediction of acute toxicity. The method "permits the prediction of rat LD_{50} for untested chemical compounds." (Toxicol. Appl. Pharmacol. 41(1), July, 1977). Why then, do millions of animals continue to be consumed in tests for acute effects?

I don't believe that routine exercises such as the LD_{50} should be honored with the title of research, because these cookbook tests certainly are not going anywhere and never have. While those who perform these tests like to view themselves as scientists, their generous self-appraisal is not generally shared by others in the research community. The Director of the NIEHS stated: "Historically, toxicology has not been viewed as one of the more exciting sciences. The brightest young people have gone into molecular biology and other things.... Toxicologists were called 'rat killers' in the parlance of scientists." (Hearings before the House Committee on Appropriations, Pt. 3, NIH, 1977). Despite the backwardness of toxic substances research, I do not observe any effort being made to modernize the research or training in this important area.

It is clear that the various agencies are having trouble recruiting new people for this repugnant work. During 1977 Oversight Hearings on biomedical and behavioral research, Donald S. Fredrickson, Director, NIH, spoke to Congress about the training of toxicologists: "... we have got to attempt to find more creative ways to attract new people into this field.... Introducing sex appeal into this particular area is a serious problem." (Oversight of Biomedical and Behavioral Research in the United States, 1977. Senate Subcommittee on Health and Scientific Research, Committee on Human Resources, June 8 and 10, 1977, Pt. 2). On September 26, 1977, the NIH announced the establishment of "The Academic Investigator Award in Toxicology" designed "to stimulate individuals... toward careers in environmental toxicology." The program provides for individual stipend awards of $25,000 per year for up to three years. As recently as January and February, 1978, EPA was still trying to attract people into the field of toxicology by establishing "a pool of exempt positions in which qualified people can be placed without going through the usual recruitment procedures and can be paid salaries not limited by the Civil Service pay scale." (FY 1979 Budget Review, EPA, Serial No. 95-H42, 1978). This tactic hardly qualifies as bringing in "new and innovative ideas" to the research community, one of the goals expressed in the pre-conference draft of DHEW health research principles in the section on research capability. In fact, toxicology today seems to be an army of mercenaries rather than a learned profession.

Any serious consideration of research capability must also take into account the continuous replication of experiments. For example, we are able to trace heat stroke experiments on animals back at least one hundred years; it really should be a little embarrassing for researchers to claim ignorance concerning heat stroke today. The same applies to radiation experiments on animals which have been going on since at least as far back as 1903. (Cited in: Arch. Pathol. 34, 1942). Testimony given before the Senate Committee on Commerce, Science and Transportation in June, 1977, indicated that the standard radiation experiments on animals have yielded little if any information about the biological consequences of the real life problem. Yet radiation researchers continue to rely on the bombardment of animals, usually with high doses over a short term, claiming that they still don't know the effects of radiation. The creation of artificial laboratory animals by the surgical fusion (called parabiosis) of two or more live animals can be traced back to the time of Galen in the 2nd Century A.D., yet these "Siamese twins" experiments continue today. The Pavlovian experiments, in which animals are made neurotic and literally driven crazy, began in the 1920's and continue to flourish. These experiments and many more have become industries in their own right, but what has this complacent replication done to enhance research capability?

As you know, the highly press-agented "animal models of human disease" are a veterinary specialty. As reported in the Journal of the American Veterinary Medical Association of April 1, 1971, "Veterinary medicine has long conducted research in this field [cancer], using animal models ...." But some scientists say that animal models don't tell why people get sick. The public has a right to know whether a chemical causes cancer or not in humans; it shouldn't have to rely on somebody's personal opinion. In this regard, Dr. Irwin Bross, Director of Biostatistics, Roswell Park Memorial Institute, testifying before the Senate on radiation hazards, said that "all the estimates of hazard were based on extrapolation - which is often a technical way of saying guess-work." (Senate Commerce Committee: Oversight Committee for Radiation Health and Safety, June 17, 1977). The public wants something better than the current "guess-work" concerning the effects of both radiation and chemicals. Under the label "comparative," the chief research capability is the ability to artificially produce disease - or injury - in every available species and to even seek more species not readily available.

There is a more insidious side to comparative research. What I and you know but as the public does not know is that veterinary medicine and veterinary research are merging with human medicine and research. The theme that veterinary and human medicine are "one medicine" is the intent of Congress, as developed in the 1960's by Senator Humphrey, who said: "Veterinary medical research is an indispensable element of research in problems of human health." (87th Congress, 1st Session, 1961). The Journal of the American Veterinary Medical Association of July 15, 1974, reported that the number of veterinarians serving on faculties of human medicine "exceeds the number of veterinarians serving in colleges of agriculture." In a letter to the editor of Military Medicine 14(8), August, 1976, a veterinarian wrote: "Every hospital which does clinical investigation, every government or state facility involved in clinically-oriented research, is a potential employer for a veterinary comparative medicine specialist, who could readily direct a clinical investigation facility at a major hospital center."

The U.S. Army Preceptorship Program in Comparative Medicine, established in 1973, provides that "in order to be a leader in human-oriented medical research, the veterinarian must have had some active hands-on clinical experience in human medicine.... the Army program endeavors to acquaint veterinarians with human disease problems by seeing some of these problems in a clinical setting, and then providing supervised human-oriented research and training." As part of this program, veterinarians participate in clinical pediatrics because "the pediatric patient [i.e. baby] and the small animal veterinary patient are similar...." (underlines supplied) (JAVMA, 170(9), May 1, 1977). In the same issue of JAVMA, an ad placed by the U.S. Army reads: "In the Army, a veterinarian is entrusted with people's health, too." How, one might ask, can veterinarians educate and train physicians when, as far as we know, they are not permitted by any state to lay a hand on a human patient? Relevant to research capability, veterinary research has been going on in this country for 200 years, and in Europe long before that. The American Veterinary Medical Association is now in its 200th year. Yet, today, veterinary medicine and veterinary research are being offered to human patients as something new. Various legislators have sponsored proposed legislation that would establish a National Center for Clinical Pharmacology. I would favor the establishment of a National Center for the Modernization of Research and Training. This is not likely over the foreseeable future; legislators tend to rely heavily on the "expert" advice of self-interest trade associations. But I see no reason why the DHEW could not stimulate innovative research, absent such legislation.

Another area that should be given serious attention is the research capability in the regional Primate Centers. Our voluminous files show that popular activities in the Centers include open-ended sexual manipulation and protein deprivation of the animals. If our files are any indication of the research capability in the Primate Centers, then those Centers should be closed down.

As you know, the NIH has issued a new Animal Welfare Policy which stipulates among other things that research on animals should be such as to yield fruitful results for the good of society, not feasible by other methods. But the NIH also reported that 60% of all biomedical research involves the use of animals. How can feasible alternative methods be developed when 60% of research funds are consumed in animal experimentation, with most of the balance used for clinical research? Little money is left for feasible "other methods" or for training in sophisticated, modern biomedical research methods that do not require the use of live animals. In that respect, the nation's research capability has indeed reached its limit.

In our ten years of existence, we have compiled massive data on sophisticated, modern non-animal-using research methods, and we believe that Government must develop a mechanism to promote these methods in order to improve and strengthen the nation's research capability. Since Congress is unlikely to activate soon in this respect, I would hope that the NIH would do it on its own.

PANEL 5

UNIFYING CONCEPTS

THE CANDLELIGHTERS

Parents dedicated to the conquest of cancer

September 29, 1978

Grace P. Monaco
Candlelighters' Foundation

UNIFYING CONCEPTS

Candlelighters, an organization of parents of children and adolescents with cancer, is submitting comments on the Pre-Conference Draft DHEW Research Principles.

We are in full support of prior public comment noted in Attachment #3 of the September 15, 1978 Memorandum to Registered Participants relating to public representation on advisory boards and councils. To insure public support of research programs, the health research community should encourage participation of as many sectors of the general public as possible. Patient participants in research programs and voluntary organizations such as Candlelighters participate in these programs in a way completely different from that of the health research community and have different experiences and opinions to offer to the decision making process.

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NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES
OCTOBER 3-4, 1978

COMMENTS OF DORIS F. TULCIN, PRESIDENT
CYSTIC FIBROSIS FOUNDATION
6000 Executive Boulevard, Suite 508
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TO THE

PANEL ON UNIFYING CONCEPTS

I. The Cystic Fibrosis Foundation is a voluntary health agency which has supported a research program for a number of years into this leading genetic killer. We recognize the need of the scientific community for stable, well-supported research opportunities. However, we believe it is essential to deal directly with the fact that biomedical research is not a seamless web in which it is impossible to predict or target the benefits expected from any individual project. Stated specifically, the solution to the question of why the Cystic Fibrosis lung is so susceptible to infection is more likely to be found through studies in immunology than through work in bone structure or neurology.

To maximize the benefit to our Nation's health from our investment in biomedical research, much of that investment must be targeted toward where it will do the most good. These areas should be determined by a two-fold test that looks both at scientific opportunity and social need.

A. The scientific opportunity test asks where good science is waiting to be done. It does little good to direct research into an applied problem where the underlying scientific questions have yet to be answered. We must continue to give adequate support to the most basic research so that building blocks for future advances will exist. Where a breakthrough has occurred, however, researchers should be encouraged to follow up and exploit the new knowledge. Also, some health problems are more susceptible to a scientific solution than others; there are certain problems and care burdens which we may never eliminate.

B. The second part of the equation asks where the need for medical advances is most substantial. Given two areas of equal scientific potential, it makes sense to weigh the funding decision in favor of research into more important diseases.

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There are two principal criteria, more sensitive than simple morbidity and mortality data, that we would suggest for determining the importance of a particular health area.

1. The first criterion is a determination of the impact of the disease measured in the aggregate years of life lost through premature death. A disease which kills a thousand people a year who are in their teens or twenties would be more significant than a disease which kills the same number of people in their sixties or seventies, and should receive more research emphasis.

2. The second test is a measure of the impact of caring for the disease on patients and the society at large. The duration of the illness, the cost of medical treatment and special requirements (such as diet) for all of the people with the disease, and the extent of disability and work-days lost caused by the health problem, would be useful measures here.

In short, the National Institutes of Health and the other components of the federal health research network should be guided by the twin stars of social need and scientific opportunity in determining which agencies and programs will receive special emphasis from the funding arena. The questions of special emphasis will be answered by someone in the governmental process, and we believe that a rational, well-justified procedure can reduce some of the swings in priorities which have concerned the scientific community in the past.

II. Another important problem that comes under the heading of "Unifying Concepts" is that of interagency cooperation. The more we learn about health problems, the more we see them resisting easy categorization. Cystic Fibrosis, for example, can be thought of as a lung disease (NHLBI), a digestive disease (NIAMDD), a genetic disease (NIGMS), a developmental disease (NICHD), a disease affecting the immune systems of the body (NIAID), and a chronic disease with mental health ramifications for both the patient and the family (NIMH). It is necessary in diseases like this to assure, through some formal mechanism, that the various program directors in areas affecting the disease are working together and are sharing their opportunities to produce the best results with the resources available.

The coordinating process will help both program directors and the researchers they work with to recognize the impact of current work on the general field. Collaborative studies could be suggested, and joint funding arranged. Needless duplication will be reduced as communication improves.

There is presently an NIH Cystic Fibrosis Coordinating Committee which meets occasionally for this purpose, and has been generally successful to date. However, this kind of activity needs to be encouraged and strengthened, and the institutional barriers between agencies need to be reduced whenever possible.

III. Finally, the federal agencies need to coordinate their research programs with those in the private sector. Although the latter may appear small, the Cystic Fibrosis Foundation until recently was supporting about 20% of the known national research into this disease, a substantial share. Further, private funds can be more flexible than federal dollars, and innovative leads pursued more easily. The directors of the private research programs need to work closely with federal program directors to assure that both the taxpayer and the private contributor are getting the maximum return for their dollars. In our case, for example, we are shifting the focus of our research program to those areas where current federal support is inadequate, rather than duplicate the outstanding work being done by NIH. This should be widely encouraged.

STATEMENT ADDRESSED TO THE PANEL ON ''UNIFYING CONCEPTS''

W. Stephen Matthews, Ph.D.
President, National Academy of Clinical Biochemistry

Again in an effort to tap the resources of the Academy Membership, the following statement was prepared by Dr. Mario Werner. Dr. Werner's credentials are without peer and include Professor of Pathology at the George Washington University Medical Center, consultant to the National Academy of Science, the Center of Disease Control as well as the National Heart, Lung and Blood Institute. Dr. Werner is a Charter Fellow of the Academy and presently is a member of the organizations Board of Directors.

Dr. Werner's amended statement from his testimony, to the Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce, House of Representatives, Ninety-Fifth Congress, First Session on H.R. 6221, can be directly applicable to the topic of this Conference.

As one attempts to interface the multifaceted human with the health care delivery system, it becomes obvious that one of the final objectives must be to improve productivity.

Since the clinical laboratory today possibly represents the most mechanized and even industrialized segment of the health care delivery system, it can be viewed as a practical example of future developments affecting health care as a whole and merits attention beyond its own intrinsic importance. A host of issues concerning the quality and cost of laboratory services require systematic investigation. However, there is a lack of resources to properly support such a study.

Findings and opinions presented by others have not provided an analysis embracing the full scope of the stated problems. Much is said about the impact upon the cost and quality of health care by regulations, by the marketplace, and even by central planning, but the body of systematic and hard knowledge in these matters remains small. Consequently, these issues should be studied in order to establish facts which could be used to improve laboratory services. However, considering the macroeconomic scope of the problems, the success of such efforts undertaken in isolation, and possibly with a provincial point of view, must remain limited.

It is urged that consideration be given to the ways in which to promote efficiency and cost containment for the benefit of the patient. A new Office of Clinical Laboratories should be established as an identifiable administrative unit within the Department of Health, Education, and Welfare, which can bring about the required applied research. In addition to raising the quality of performance for all laboratories up to the current state-of-the art, the tasks of this Office will involve improving the current state-of-the-art itself to achieve cost containment through improved efficiency. This goal can best be attained by incorporating an Applied Research, Development and Dissemination Division within the Office of Clinical Laboratories.

Today, the challenge again is to create conditions which will foster the development of a more advanced basis of knowledge through applied research on issues such as the following:

First, despite the obvious implications, very little research on the clinical utilization of laboratory procedures has been performed. For instance, the practice of administering a standardized battery of laboratory tests to every patient upon admission to the hospital has been justified by the reasoning that result from such tests precipitate medical actions. However, currently, no satisfactory statistic of such medical followup on positive findings are available. Without this information, the identification of the economic cost of malutilization is impossible. As far as the patient is concerned, a disregarded true-positive laboratory finding is undistinguishable from a false-negative laboratory finding. In addition to analyzing utilization, new methods to postively insure proper followup of available information merit a high priority from an economical point of view.

Second, standards for the evaluation of quality must be developed individually for different assays on the basis of clinical relevance. Even though quality always comes at a price, performance is still commonly considered from a perfectionistic point of view. In reality, the medical use to which laboratory information is put

ALWAYS DEFINES A CEILING BEYOND WHICH IMPROVEMENTS OF QUALITY HAVE NO PRACTICAL VALUE. RECOGNITION OF THE LIMITS IMPOSED BY UTILITY WILL CONTAIN COST.

THIRD, THE ANALYSIS OF TRADEOFFS BETWEEN COSTS AND BENEFITS OF ALTERNATE WAYS OF UTILIZING LABORATORY RESOURCES IN THE MANAGEMENT OF SPECIFIC DISEASES HAS SCARCELY BEEN INITIATED. FOR INSTANCE, THE EXPENSES OF DRUGS ACCOUNTS FOR ABOUT 8 TO 10 PERCENT OF TOTAL HEALTH CARE COSTS. IT IS KNOWN THAT STANDARDIZED DOSAGE REGIMENS PRODUCE BOTH UNDERMEDICATION AND OVERMEDICATION IN A SIGNIFICANT PERCENTAGE OF PATIENTS. WITHOUT EVEN CONSIDERING THE MEDICAL IMPLICATION OF SUCH MALUTILIZATION, THE ECONOMIC BENEFITS OF INTRODUCING ASSAYS OF DRUG CONCENTRATION IN BLOOD TO TITRATE THERAPY MERIT ATTENTION. AS MUCH AS EIGHT PERCENT OF HOSPITALIZED PATIENTS ON MEDICAL WARDS MAY BE THERE BECAUSE OF DRUG INDUCED ILLNESS, A SO-CALLED ''DISEASE OF MEDICAL PROGRESS''. TO JUST LOOK AT ANOTHER PART OF THIS PROBLEM IN REALISTIC TERMS, IF INEFFECTIVE UNDERMEDICATION WERE TO ACCOUNT FOR ONLY TEN PERCENT OF THE OVERALL DRUG USE, THIS WOULD REPRESENT ABOUT A ONE BILLION DOLLAR WASTE.

FINALLY, RESEARCH ON THE COST-EFFECTIVENESS OF LABORATORY SERVICES MUST INCLUDE A COMPREHENSIVE ANALYSIS OF THE IMPACT OF THESE SERVICES ON HEALTH CARE. IN DEALING WITH THIS QUESTION TOO LITTLE ATTENTION HAS BEEN PAID TO THE PROBLEMS OF OFFSETTING COSTS AND BENEFITS INCURRED BY RETAINING AND EXPANDING THE UNCHANGED CONVENTIONAL SYSTEM. IN REALITY, IT IS FUTILE TO OPTIMIZE PARTS OF THE SYSTEM IN ISOLATION. THE REAL VALUE OF A TEST IS IN ITS CLINICAL PAYOFF. WITHOUT THIS PERSPECTIVE, CHOICES DETERMINING THE COST OF HEALTH CARE WILL CONTINUE TO BE MADE IMPLICITY, CLOAKED BY PRECEDENT AND ESTABLISHED PROCEDURE.

THE PROMOTION AND COORDINATION OF APPLIED RESEARCH, DEVELOPMENT AND DISSEMINATION PROJECTS ON METHODOLOGY AND UTILIZATION WILL PERMIT A VIGOROUS ATTACK ON THESE AND OTHER ISSUES. MUCH ATTENTION HAS FOCUSED ON EFFECTIVENESS, SPECIFICALLY QUALITY OF LABORATORY DATA. SIMILAR ATTENTION TO COST IS NOW MANDATORY. IN THE FACE OF FINITE RESOURCES AND A POTENTIALLY LIMITLESS DEMAND, CHOICES MUST BE MADE AND PRIORITIES SET ON THE BASIS OF SCIENTIFICALLY ESTABLISHED DATA AND PRINCIPLES.

Testimony presented by Mahlon B. Hoagland, M.D. President and Scientific Director, Worcester Foundation for Experimental Biology, in behalf of the Delegation for Basic Biomedical Research.

Before DHEW's National Conference on Health Research Principles, October 3-4, 1978.

During the past ten months a small group of distinguished scientists and surgeons* has been active, in discussions with members of the administration and of Congress, attempting to bring national attention to the importance of basic research. As their spokesman I submit the following comments:

It is abundantly clear to medical scientists and a significant segment of the public that substantial further improvement in the health of the American people, with attendant cost reductions, awaits the acquisition of much more basic biological knowledge about normal and abnormal cell and body function. The major killers and disablers like cardiovascular disease and mental illness, cancer, and arthritis are now the enemies, as once were other equally fearsome ills. But they can be controlled and and defeated by the methods of basic research.

Our optimism and confidence in the effectiveness of basic research is rooted in the history of its accomplishments. Consider: the virtual elimination of all the major infectious diseases; the impact of vitamins and other nutritional factors on human health, including the lengthening of life expectancy; the availability of Xrays for diagnosis and treatment; the ability of women to control their childbearing; organ transplantation and cardiovascular surgery; the successful treatment of Rh disease of the newborn; improvements in treatment of hormonal abnormalities; and the chemical control of mental illness. These remarkable triumphs are the result of the free exercise of individual curiosity, imagination and experimental ingenuity.

Basic research produces the library of knowledge from which applied research borrows to bring help to the suffering.

There is no question that the diseases we now confront present more formidable problems to the scientist than those already vanquished. But it must be remembered that during the last 40 years our knowledge base has grown at an astonishingly rapid pace, presaging early application to the more intractable problems of human disease. Government-supported research in: the structure and function of cellular membranes; the cellular control of gene expression; chemical and viral carcinogenesis; mode of hormone action; immunology; genetics; and neurobiology now hold particular promise for the eventual prevention, cure or control of cancer, cardiovascular disease, genetic disease, arthritis, endocrine disorders, allergic and autoimmune disease and mental illness.

In spite of the overwhelming evidence of the effectiveness of basic science in eliminating and controlling human ills, we as a nation are spending only one-half of 1% (about $1 billion) of our health care expenditure (about $200 billion) on basic research. While the budget of the National Institutes of Health has risen over the last decade, the real dollar support for basic research has failed to keep pace with the nation's potential for doing that research. Our shrinking resources are increasingly directed toward applied "research" aimed at limited, short-term objectives.

At this stage in history our knowledge base is still inadequate to fathom the complexities of cardiovascular disease, cancer, arthritis, etc. It follows that applied research programs capable of providing definitive practical benefits are very limited in number and scope. Yet government continues to experience rising pressure to sponsor premature, scientifically unsound and inordinately costly applied projects.

The U. S. Government has created and generously implemented the most effective device known to man for initiating and nurturing the best in research: the scientist-initiated, peer-reviewed project grant. In recent years this unique support vehicle has found itself in competition with program-project grants, center grants and contracts, support vehicles better suited to bureaucrats than to scientists.

In view of the above considerations we urge the Department to give particular attention to the following in a multi-year plan for health research:

1. A substantially greater proportion of National Institutes of Health funds should be used for funding scientist-initiated project grants (R01 grants). This is particularly applicable to the National Cancer Institute which has been spending substantially less on R01s than have the other institutes.

2. Greater stability of support of biomedical research is urgently needed. This would require that the National Institutes of Health consider more carefully the effect funding in one year has on the commitment base in the next two or more years. Consideration should be given to funding more grants for periods longer than three years; providing other forms of institutional funding like the Biomedical Research Support Grant; reinstituting career awards; and increasing the number of career development awards. Multi-year planning for research support can of itself, in principle, help in reducing instability.

3. The peer review system is vital to a strong research effort and the efficiency of its operation should be diligently nurtured. Adequate peer review should apply to all National Institutes of Health awards.

4. A continued supply of highly qualified scientists for the biomedical research enterprise must be worked into a multi-year plan.

Respectfully submitted,

Mahlon B. Hoagland, M.D.

*List of Delegates attached

Dr. Wallace C. Frasher, Executive Vice President

TESTIMONY FOR THE AMERICAN HEART ASSOCIATION

Conference convened by Secretary of HEW Califano, October 3 and 4, 1978

Panel 5 -- Unifying Principles

Mr. Chairman, Ladies and Gentlemen, I am delivering this testimony on behalf of the American Heart Association. The American Heart Association is a voluntary health agency established in 1948, whose mission has continuously been defined as an effort to reduce death and disability due to heart disease. The Association has recognized research as a fundamental necessity for discharging this mission since its inception. Currently and for the last several years, the Association has mandated 57% of funds available at its National Center to be invested in research. In addition, substantial sums are invested in research by the local Affiliates of the organization, of which there are 55 throughout this country. This year, the total investment of the American Heart Association in biomedical research is in excess of $21 million.

In testifying before this Panel, whose purpose is to address unifying principles leading to successful planning for health research, the Association recognizes that this Panel clearly has the least well defined, but probably the most important task of the panels assembled here. Unifying concepts, if they are to have any merit, must, of necessity, delineate the processes for determining priorities for support among complementary kinds of health research. The concepts this Panel adopts, therefore, must be clear and precise enough that the Department of Health, Education and Welfare can use them to recommend priorities. The concepts from which those priorities stem in addition, then, must be clear and precise enough that the Congress of the United States can also be convinced that decisions based on the operation of those principles can be accepted as reasonable and represent a compelling rationale for legislative support.

The American Heart Association suggests as a first principle, the concept that the investment in health research by the government must be of sufficient magnitude to insure optimum flow of new scientific information into the health care system.

The primary source is in basic research and that must be supported, but it is clear that in a complex society with health needs such as ours, there must also be other kinds of research. In these different kinds of research there are different time scales to accomplishments. Basic research into fundamental principles must represent a long-term investment. The time scale is predictively shorter in applied research of limited objectives. The magnitude of the investment necessary to support each of these kinds of research needs to be separated and insured over the appropriate time scale for the activity. In the planning booklet for this conference, one of the concepts suggested as a unifying concept is that because of the opportunity of targets of advantage, the system of planning must provide flexibility and adaptability for the changing needs of research. However, it must clearly be spelled out that flexibility and adaptability, in order to pursue exciting new leads, must not depend on curtailing longer time ventures which need to be supported in order to accomplish their ultimate good, and this, of course, relates to the necessity for stability in the funding of fundamental biomedical research.

In the current situation the adoption of Principle #1 implies that a larger proportion of the health dollars available to the federal government in this country should be allocated to health research. To do otherwise clearly is to fall into the trap which has been eloquently defined by the Chairman of this Panel, Dr. Louis Thomas, as settling for expensive and costly half-way technology by stopping short of an investment which is sufficient to do the studies which will lead eventually to an understanding of the causes and means of prevention of these disease states. This kind of direct prevention of disease clearly is the ultimate answer to cost containment in health care.

The American Heart Association suggests as Principle #2 in the field of unifying concepts, that the evaluation of health research priorities should originate in an objective evaluation of the scientific merit of proposed studies.

In this recommendation, the Association takes serious exception to a proposal recorded in the draft document originating with the Department of Health, Education, and Welfare Agencies, carried on page 22 of the Conference Proposal. This statement suggests that social problems or needs should weigh significantly in determining the priorities for support of health research. To this suggestion the Heart Association would respond that research is a scholarly activity in which exhaustive analysis of the current state of knowledge precedes the design of an experimental approach. These two activities must converge in order to generate a program which has any hope whatsoever of advancing our knowledge and our ability to confront health problems. The ability to evaluate and to distinguish these two components of a program must be provided as the initial stage of analysis quite independent of any perceived social pressure or problem or need. The Heart Association strongly suggests that the public good will be best served in the long run by support of the best science.

The experience in the American Heart Association for the past 30 years has strongly suggested that dedicated scientists can be assembled who are capable of submerging their own partisan disciplinary values. These groups of individuals, in setting priorities for research activities in the Heart Association, have frequently managed to achieve an honest consensus and set priorities according to the merit of the science of the programs proposed quite independent of any considerations of geography or scientific discipline.

It is the viewpoint of the American Heart Association, therefore, that the assessment of priorities for health research and the concerns of the Deparment of Health, Education and Welfare, should originate as judgments of scientific merit made by such an objective and impartial body.

Clearly, the practical implication here is a system modeled after the peer review and technical consensus system, but whose concern is somewhat broader than a partially mission-oriented function. The Association makes no effort here to define the characteristics or composition of such a body. The Association is, for the time, content to submit a strong recommendation that the Department of Health, Education, and Welfare undertake the problem of reaching such a definition and organizing such a body. Having done this task, the Association suggests that it should be mandated that the priorities for funding of health research recommended by such a body, should be respected by all other agencies in the government, unless an overwhelmingly rational contrary opinion can be demonstrated.

Principle #3 and the final principle proposed here today, is that there should be continued and reinforced cooperation between federal health research agencies and the third sector as defined by David Rockefeller, where the third sector characterizes the voluntary agencies. Clearly, the voluntary components of our society are deeply involved in mission-oriented health research.

Clearly, then, the common objectives of federal agencies involved in supporting health research and the voluntary agencies with similar objectives, need to lead to continuous recognition of each other through mutual involvement of the government agencies and the voluntary sector in consultation. This implies that the mechanisms must be provided for the timely two-way exchange of information so that each is capable of conducting its own independent role, but in which each can reinforce the other in areas of common interest.

Clearly this kind of cooperative support of the research mission is of advantage in that it can use the unique capability of voluntary health agencies to project a strong and appealing message to the public in these United States which each year gives generously to these various causes. The utilization of information about the thrust of the health research enterprise made known generally through the work of the voluntary health agencies, clearly will work to the advantage of all who have an abiding concern in the enhancement of health research in this country.

On behalf of the Heart Association, I thank the conveners of this conference for the privilege of testifying in this important venture.

/jf

Leonard D. Fenninger, M.D.
American Medical Association
Panel V
Unifying Concepts

Synthesis and Coordination of Science and Technology

It is inevitable that different emphases will exist in the pursuit of new knowledge and its eventual application. Knowledge which affects health and disease is extremely diverse as are the technical skills and procedures which derive from the knowledge. The interests and abilities of individuals developing and using knowledge and technologies, the concerns and responsibilities of institutions, organizations and agencies and of local, state and national governmental bodies contribute to and share in the diversity.

This diversity has led inevitably to specialization of individuals and institutions and has been the great strength of science and technology in the United States. With the need to conserve resources there is also need to synthesize knowledge and technology and encourage coordination of efforts in biomedical and other scientific research. At the same time individuals and the organizations and institutions in which they work should pursue those areas of investigation in which their capabilities and interests lie. All components of the biomedical enterprise should be identifying gaps in knowledge, areas which can be effectively pursued, and sharing new knowledge as it is gained. Coordination, to be effective, must first occur in the community of scientists and in their institutions and organizations. It cannot be done by the Federal Government in the absence of coordinated and cooperative efforts among scientists themselves. Legislative authorities for research, policies of federal and of the public and private agencies should foster coordination and cooperation. Special narrowly categorical legislation and funding policies tend to limit coordination and in some cases make it virtually impossible in local settings.

As a general principle legislation and funding policies should be as broad as they can be while assuming reasonable accountability on the part of those using the nation's limited resources. This is particularly true of the support of fundamental research, wherever that support may be generated. Flexibility is essential in the provision of resources if serendipity is to be useful (as it must be in exploring new ideas and testing new hypotheses). Non-governmental bodies should have ample opportunity to present information and evidence in the formation of public policy and research efforts. Governmental agencies have a responsibility to coordinate their efforts and policies if resources are to be well and effectively used. This is an obligation of the highest order for all who are using resources to pursue scientific knowledge and technology and to apply this knowledge and the technologies derived from them to improve health and to prevent or contain illness.

Such coordination should not limit diversity of efforts but should assist in relating policies within the Federal Government to one another and in relating federal efforts to those being conducted by the public and private agencies, organizations and institutions.

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October 3, 1978

STATEMENT FROM AIRI TO NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES. PANELS ON FUNDAMENTAL RESEARCH AND ON UNIFYING CONCEPTS.

The following recommendations on Health Research Principles were unanimously approved at the Annual Meeting of the Association of Independent Research Institutes on September 15, 1978.

1. Greater STABILITY of support of biomedical research is urgently needed, i.e., NIH should consider to (a) fund more grants for periods longer than three years and so inform study section membership (b) reinstitute career awards for outstanding Scientists and increase the number of career development awards (c) seek an increase in BRSG funds (d) carefully consider the effect funding in one year has on the commitment base for the next or more years (i.e., additional equipment funded with FY 1979 funds would not increase the commitment base for future years).

2. A substantially greater proportion of NIH funds should be used for funding scientist-initiated project grants (ROls). This is particularly applicable to NCI, NIEHS and NIDR. Most other institutes spend at least 60% of their appropriation for this purpose.

3. The peer review system is vital to a strong effort and its operation should be made as effective as possible. ADEQUATE peer review should apply to ALL NIH awards.

4. A continued supply of highly qualified and trained scientists for the biomedical research enterprise must be worked into the multi-year plan.

I would like to add that we would like to see NIH pay particular attention to how the FY 1979 funds will be distributed. The possibility of funding applications to a priority of 250 during FY 1979 raises the specter of not being able to fund much higher priority grants during FY 1980. The referral office at NIH should be encouraged to more frequently make dual or triple assignments so that applications funded by the different Institutes are of similar high quality and do not differ substantially in their priority rating.

Our insistance in allocating a larger proportion of the NIH appropriation to ROls is that this is the most economical way to fund high quality basic (and also applied) research. It focuses on high quality and does justice to basic or fundamental research. It does not call fundamental any research not included in the clinical trial index as the newly coined "Science base" term does.

The comments just made should also be extended to ADAMHA.

Sincerely yours,

Federico Welsch, M.D., Ph.D.
Governmental Affairs Liaison

FW:mc

cc: Dr. Lewis Coriell, President
Dr. Mahlon Hoagland, Past President
Dr. Herbert Hauptman, Vice President

PANEL: "UNIFYING CONCEPTS"

Remarks of Dr. Gerald Weissmann
Professor of Medicine
Director, Division of Rheumatology
Department of Medicine
New York University Medical Center

Dr. Thomas, members of the panel, guests.

My name is Dr. Gerald Weissmann of New York University and I speak as a member both of the American Rheumatism Association of the Arthritis Foundation and the Public Policy Committee of the American Society for Cell Biology. In the midst of a discussion of "Health Research", I should like to argue for one overriding "Unifying Concept". It is the principle of science for its *own* sake, for without protection of *that* concept, no other real or imagined benefit of health research will follow. I am asking you to consider spelling out in your report a strong, overriding plea for freedom of scientific inquiry, whatever its imagined consequences.

Until recently, the biomedical scientist has been quite certain that any new knowledge he acquired as to the nature of living things could not help but be useful to the general welfare, and that such *"utilitarian"* values constituted a moral guarantee for his intrusions upon the natural world. In consequence, he was required only to follow his *"esthetic"* concerns for the elegant experiment, the beautiful proof, the unshakable theory. Recent events have unsettled this agreeable view, but I am arguing here that there is life in it yet.

There is ample support for the idea that *"science for its own sake"*, the esthetic view, yields utilitarian benefits. Research not oriented towards disease, but into the nature of soil fungi, gave us streptomycin, inquiry into the nature of cells in culture led to the Salk vaccine, and studies of the cell cycle in onion root tips have eventuated in the rational treatment of leukemia. Such examples, and at least three-score others which decorate our recent history, have reassured the community of biological scientists that our general enterprise is intrinsically benign. As a corollary, the scientist is persuaded that if he performs his task professionally, by doing *well*, he is doing *good*.

Indeed, the game of science has been played in obedience to a set of rules which has remained uncluttered by any ethical stricture save one: thou shalt not fudge the data! The professional code of the scientist has been a stringently esthetic one. It has rewarded the individual imagination for coming up with reproducible experiments. And that kind of imagination has, until recently, been considered by one and all to resemble that of the creative artist, no more - and no less - in the service of temporal, social mores. W.H. Auden has summarized this attitude, removing this creative effort to another realm:

> *"Both science and art are primarily spiritual activities, whatever practical applications may be derived from their results."*

This state of affairs - still quite satisfactory to me - has now become so strongly challenged, that the esthetic values of biomedical research have been edged into disrepute. Indeed, even the utilitarian ends of our science - the manipulation of nature for the eradication of what we perceive as its errors - have been attacked by environmentalists, humanists, and the new theologians. Energized a decade ago by the folly of our technology in Viet Nam, critics from without have been joined by the disenchanted young from within the perimeter of science.

The disenchantment of scientists and their lay critics culminated in the fuss over recombinant DNA which moved from the shores of Asilomar to the halls of Congress. What began as a brave, internal, effort to face ethical problems raised by gene-splicing has slowly developed into a broad social movement (in the words of June Goodfield)

> *"...'to blow the whistle'. To taper off that curve of infinite environmental manipulation".*

For the first time in recent democratic history, there is a good chance that some, perhaps benign, authority will legally declare to the biological scientist: thou shalt not do this experiment, because it is ethically wrong to muck about with our genes or inconvenient to discuss the heritable bases of behavior. But the most frightening reification of these social, and ethical anxieties would be the imposition, by means of external authority, of an overall plan or set of priorities upon the scientist. Such a plan, with the dual aim of pleasing both the thrifty and the ethical, will assure us - we may presume - that after his quest for the Golden Fleece the researcher will neither emerge with steel wool, nor come back to Medea.

Long-range plans, overlaid with ethical considerations, are based on the assumption that the utilitarian output of the scientist's profession has some *unique* social implications, and that these implications require society at large to set some limit on his esthetically motivated quest. But are the social consequences of scientific research different *in kind* from those of other scholarly pursuits or the creative arts?

Professional historians suggest the utility of their narratives for an understanding of the present; professional philosophers (of some schools, at least) believe in the usefulness of their metier for proper conduct; and social scientists agree that their analyses are of use in the amelioration of political problems. But can we say with certainty that the contributions of Fichte, Nietzsche, and Spengler had less grave consequences for the orderly flow of social progress than even the most lurid results immaginable of our biological inquiries? Cyril Connoly has quipped:

> *"Le coeur a ses raisons-and so have rheumatism and the 'flu'".*

Since some of us look into the reasons of rheumatism for the reasons of our heart, it is extravagant for the sciences to claim - at least with respect to subject matter - a measure of the license granted to the arts?

Does this imply that I advocate complete license, complete liberty with respect to what kinds of research biomedical scientists should pursue? Let me advance this claim, as phrased by Auden

> *"liberty is prior to virtue; i.e. liberty cannot be distinguished from license, for freedom of choice is neither good nor bad, but the human prerequisite without which virtue and vice have no meaning. Virtue is, of course, preferable to vice, but to choose vice is preferable to having virtue choose for one."*

Such a completely libertarian view is clearly counter to the temper of our time. We must, indeed, accept the rational bases for the general disenchantment of our culture with the products of science pursued for its own ends. The wonderful folks who gave you (however indirectly) the bomb of Hiroshima, the laboratory of Auschwitz, and the psychiatry of the Gulag Archipelago are not generally trusted to keep their new genetic tools locked safely in the academic cupboard.

But from where did the counter-forces arise to these overt excesses? To a large extent, scientists themselves, acting in response to a code of moral values they share with others, have "pulled the whistle" on more of these outrages. The Atomic physicists, by means of their Bulletin, have resisted the proliferation of their monster, biomedical scientists have propagated the Helsinki principles, and psychiatrists have exposed the social mischief of the mental health commissars. The motivating force behind these ameliorative actions has been, I believe, the sense of human ethics with which our society at large is impregnated. The character and manners of our scientists are probably determined more by the general culture of which they are a part than by any unique sense of scientific ethics. A society gets not only the government, but the science, it deserves.

Our only guarantee that new knowledge will not be gained at the expense of human values is the integrity of that network of values in which all our inquiries are enmeshed. This is to argue that we should impose no pre-emptive restrictions on the *kinds* of new knowledge to be sought. If we wish, for example, to prohibit certain investigations on human subjects by our physiologists because their Nazi counterparts violated any reasonable code of behavior, we may be granting the Nazis a posthumous victory they do not deserve. Of course, our science should not design experiments that are trivial, dangerous or dehumanizing. However, these adjectives are best defined by the consensus of society at large. And if that concensus be justly derived, we can expect that the community of scientists, as citizens, will agree.

Finally, I am convinced that the culture of science, which engages at least as much of our population as does the humanist culture, is worth nurturing for its own sake. The unravelling of the genetic code, the elucidation of cell structure and metabolism, our analysis of how nerves make muscles twitch or speech possible, constitute, I submit, cultural achievements no less imposing than the mosaics of Ravenna or the cathedrals of France. At a time when the arts of our decade are devoted to the production and analysis of works related to self - inquests into narcissism - the objective triumphs of our science are perhaps even more to be cherished. We will, I daresay, not achieve the utilitarian ends of our science: freedom from hunger and disease, less anxious youth and sturdy age, without adopting the risky, libertarian view that there shall be no bounds and no *a priori* plans as to what scientists need to know. Motivated by esthetic considerations to reach the aims of utility, scientific research will come (in the words of our Chairman)

> *"if the air is right ... in its own season, like pure honey."*

Presented by Michael Gordon, Ph.D.

for

The Society of Teachers of Family Medicine
and

North American Primary Care Research Group

The Society of Teachers of Family Medicine is comprised of approximately 1,440 members, all involved in family medicine education and training programs. It is an interdisciplinary society with members representing medicine, social work, education, pharmacy, administration, nursing, the behavioral and social sciences, and other fields. Our members pursue their professional activities in medical schools, community hospital teaching programs, and in a great variety of community-based teaching practices. In the spring of 1978 the Research Committee of the Society was charged to review and articulate principles and strategies which might profitably govern the research efforts of those in our discipline. That work began during the past summer and was accelerated in response to Secretary Califano's request for input into the development of a federal strategy for supporting health research. The document presented here has been prepared by a task force of the Society and will be submitted to the organization's board of directors at its next meeting in October, 1978. Many of the members who are involved in research also participate in the North American Primary Care Research Group. This testimony is a joint effort of these two organizations.

FOCUS 5: UNIFYING CONCEPTS

Feinstein and Beck[1] have described a spectrum of medical or health-related research as illustrated here across the top of Figure 1. On one end, much medical research deals with understanding the pathogenesis and mechanisms underlying health and illness. On the other end of that spectrum are researchable questions concerning public policy for deploying medical and health care resources. In between are questions of clinical management strategy and those pertaining to organization and administration of health care services. All points along this spectrum contain legitimate and important questions for medical and health care research. We would recommend that federal support for health research maintain a balance across this entire spectrum.

Similarly, there are multiple disciplines or traditions of research which may be brought to bear on these researchable questions. Medicine has exploited to great advantage the biomedical sciences (for example anatomy, physiology, and biochemistry) in exploring the mechanisms of disease and clinical strategies for dealing with disease. Epidemiology has made great contributions across the entire spectrum of medical research. If we can accept the goal of Federal Health Research Policy to be the improvement of public health, we must soon recognize that, due largely to the past success of biomedical research and its applications, the largest gains in public health yet to be made lie in studies of behavioral, social and environmental determinants of health. Many of the questions we now face will require an even broader interdisciplinary attack. We therefore believe it will be important to support basic and applied research in a wide range of disciplines including the behavioral sciences, social sciences, philosophy and ethics, and others.

In all research, the first and critical step is asking the right questions. Recognizing the researchable question, identifying the important problems, uncovering the illuminating clue -- all of these are more likely in health research if population-based monitoring systems are readily available. Continuing epidemiologic surveillance is an important underpinning of the federal research effort and we recommend that funding be provided to maintain existing systems, such as the National Ambulatory Care survey and support the development and perfection of new ones.

The high cost of health care has now captured the attention of all. Therefore, many efforts are directed toward measuring effectiveness of health care as related to its cost. A problem arises in that our current measures of outcome, such as death and days of disability, are inappropriate measures for many health-related interventions. New indices of health status are needed which take into account the wide diversity of biologic, socio-cultural, and behavioral phenomena which make up our concept of health.

Responsibility for funding this health research effort should be shared by a variety of entities within our society. This should include public agencies, private philanthropic organizations, and industry. However, the experience of recent years has indicated that it falls to the federal government to fund a majority of these activities (approximately 60 percent). We do not see any realistic possibility of change in the future. Given that the benefits of such research are shared on a nationwide basis, it would seem appropriate to continue such federal support in the future.

Inherent in all of these statements is our strong belief that progress in medical and health-related research requires and will continue to require interdisciplinary collaboration. That is, it will require researchers from various traditions and disciplines to work together. It will also require cross training of individuals who can bridge clinical and basic, social and biomedical, and other combinations of scientific traditions.

In summary we suggest:

1. Federal support should maintain a balance across the entire spectrum of health research.

2. That support should be available for multiple disciplines of research including the biomedical, behavioral, social and other sciences in order to address complex health problems.

3. Population based epidemiologic surveillance should underly the federal health research effort.

4. Interdisciplinary training and collaboration should be encouraged.

5. The federal government should reaffirm that the benefits of health research are shared on a nation-wide basis and thus constitute an important national commitment.

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[1] Feinstein, A.R. and Beck, J.C.: the Robert Wood Johnson Clinical Scholars Program. New England Journal of Medicine, 293:1149, 1975.

PUBLIC TESTIMONY

TO

UNIFYING CONCEPTS PANEL

OF THE

NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

3 OCTOBER 1978

BY

COLONEL ROBERT E. GLASGOW, MA
PRESIDENT

DOWN'S SYNDROME CONGRESS

DISTINGUISHED PANEL, LADIES AND GENTLEMEN. I SPEAK TO YOU AS A PARENT OF A DOWN'S SYNDROME CHILD AND PRESIDENT OF THE DOWN'S SYNDROME CONGRESS. THE DS CONGRESS IS A NATIONAL ORGANIZATION WITH MEMBERSHIP IN EVERY STATE AS WELL AS SOME FOREIGN COUNTRIES. FOR THE SAKE OF TIME I HAVE ENCLOSED A LISTING OF THE PURPOSE OF OUR NOT-FOR-PROFIT ORGANIZATION.

LATE IN AUGUST OF THIS YEAR I SUBMITTED A COPY OF THE DS CONGRESS 17 APRIL 1978 TESTIMONY TO THE HOUSE AND SENATE HEW APPROPRIATIONS COMMITTEE TO DR FREDRICKSON FOR YOU ALL TO CONSIDER IN YOUR MOST WORTHWHILE AND CHALLENGING ENDEAVOR.

MY REVIEW OF YOUR DRAFT DHEW HEALTH RESEARCH PRINCIPLES AND THE SUMMARY OF GENERAL THEMES OF PUBLIC SUGGESTIONS REGARDING HEALTH RESEARCH PRINCIPLES AS WRITTEN IN THE SEPTEMBER 15, 1978 MEMORANDUM TO REGISTERED PARTICIPANTS RESULTS IN THE FEELING THAT THERE IS NOT MUCH MORE TO ADD TO WHAT YOU AND WE PRECEIVE AS IMPORTANT.

WE FEEL SO STRONGLY THAT PUBLIC INPUT TO RESEARCH PRIORITIES IS IMPORTANT THAT WE HAVE RECENTLY NOMINATED MEMBERS OF OUR ORGANIZATION AS CANDIDATES ON THE NATIONAL ADVISORY CHILD HEALTH AND HUMAN DEVELOPMENT

COUNCIL. DOWN'S SYNDROME IS A SIGNIFICANT PORTION OF THE MENTAL RETARDATION COMMUNITY AND THAT COMMUNITY CONSTANTLY NEEDS A SPOKESMAN TO HELP INCREASE MR AND DOWN'S SYNDROME RESEARCH.

THE DOWN'S SYNDROME CONGRESS FEELS THAT INADEQUATE ATTENTION TO A COORDINATED EFFORT TO DETERMINE THE CAUSES AND PREVENTION OF DOWN'S SYNDROME HAS TRANSPIRED. ACCORDINGLY, WE HAVE STRESSED TO THE CONGRESS OF THE UNITED STATES AND NIH THE NEED FOR INCREASED EFFORT. RATHER THAN JUST SUGGEST TO OTHERS WHAT TO DO THE DOWN'S SYNDROME CONGRESS RESEARCH COMMITTEE RECENTLY DEVELOPED A PAPER FROM A SURVEY OF PARENTS, PHYSICIANS, EDUCATORS AND PSYCHOLOGISTS KNOWLEDGEABLE IN THE FIELD OF DOWN'S SYNDROME. WE HAVE ESTABLISHED PRIORITY GOAL STATEMENTS AS THE DS CONGRESS RESEARCH PRIORITIES.AND EXPECT OUR BOARD OF DIRECTORS FINAL APPROVAL NEXT MONTH. A COPY IS PROVIDED TO EACH OF YOU. ALTHOUGH THE SURVEY WAS CENTERED AROUND RESEARCH PRIORITIES, THE MOST IMPORTANT GOAL ESTABLISHED WAS THE NEED FOR A SUBSTANTIAL COORDINATED RESERACH EFFORT CONTROLLED BY A DOWN'S SYNDROME RESEARCH AND DEVELOPMENT CENTER. THIS CENTER WOULD PROVIDE QUALITY CONTROL LONGITUDINALLY AND COULD COORDINATE RESEARCH AND DISSEMINATE ACCURATE DATA. THIS CENTER CAN OPERATE WITHIN THE CURRENT MENTAL RETARDATION RESEARCH INSTITUTE STRUCTURE, TO BE MORE COST EFFECTIVE, OR AS A SEPARATE DEDICATED CENTER. IT IS NOT EASY TO FIND OUT WHAT IS HAPPENING AND WHAT IS ACCURATE INFORMATION REGARDING DOWN'S SYNDROME. SUCH A CENTER FOR DOWN'S SYNDROME COULD SATISFY MANY OF YOUR PRINCIPLES LISTED AND DISSEMENATE TIMELY INFORMATION.

HEALTH RESEARCH MUST BE CONTINUOUS, COORDINATED WITH PUBLIC INPUT AND MUST BE DISSEMINATED TO THE SCIENTIFIC AND PUBLIC COMMUNITIES. A CENTER CAN REGULATE APPROPRIATE BALANCE BETWEEN BASIC AND APPLIED RESEARCH AND FACILITATE MANGAGEMENT OF YOUR PRINCIPLES.

My name is Robert Rice, and I represent Family Service Association of America, whose membership comprises nearly 300 family service agencies throughout North America.

One way of examining the task of health research is to conceive that health and illness "happen" with reference to disease-specific mechanisms. Another perception is that health "happens" because of a combination of lifestyle circumstances. Both of these viewpoints are necessary to appropriate health research, but it is to the latter that I wish to speak.

Moving from a research base in epidemiology, a viewpoint often described as "community health" has been derived, and is implicit in the preliminary materials leading to this conference. I wish particularly to call attention to a means by which many of the complex variables of the health environment are brought to bear upon the individual--that occurs to a great extent within families. Theory about families is beginning to emphasize how the family acts as a mediating institution, helping its individual members to connect with and interpret a great variety of social institutions, using many varying value systems. The results may be helpful or hurtful to the larger society or family members. One major aspect of this activity by families can be found in an examination of health services delivery as actually performed. Families inculcate health-related behaviors from the earliest age and, moreover, lay the groundwork for high levels of disease-producing stress for individuals, or means of capably dealing with stress.

Despite the fact that the health-related literature is replete with suggestions about connections with families in care regimens, health fields have not truly concentrated on the family except as an ancillary aspect of care procedures. Neither have they developed large-scale alliances with other disciplines and organizations, such as ours, with central program attention to family life. Yet most health care is delivered by families, just as proclivities to various states of health or disease are programmed by families for both children and adults. This would suggest, I contend, greater attention to how families can contain a health or disease-producing function. Attention to this can occur throughout the research continuum described in preparatory materials for this conference. If our health delivery policies are to become more effective, it seems to us that families must be more clearly acknowledged as primary health care resources and/or producers of disease. NIH preliminary materials emphasize the need to strengthen relationships between federal research and the public; greater consideration of families in health delivery might go far toward realizing such a goal.

The National Institute of Child Health and Human Development has provided research emphasis on some family-related matters, but this has been particularistic rather than holistic, and has tended to consider families as ancillary to more primary interests in child and maternal health, mental retardation, and population matters. This differs from the exploration of the central role of families, viewed as care systems in their own right, that we advise.

I hope this does not sound simple; understanding and effecting how families interact with other social institutions is full of ethical controversy and largely unexplored research questions. Exactly because it is so difficult, we need a solid research base to ensure that we help effectively, but do no harm in the process.

NATIONAL CONFERENCE ON HEALTH
RESEARCH PRINCIPLES
October 3, 1978

Fundamental Research -- Unifying Principles

Ernst Knobil, President-Elect
The American Physiological Society

In its 1976 report, the President's Biomedical Research Panel reaffirmed the widely and tenaciously held view that fundamental, or basic research in the biomedical sciences, including behavior, yields ". . .The science base upon which to build improved technologies for the prevention and cure of disease." It went on to say that: "Before there can be intelligently conducted applied research, before there can be demonstrations or clinical trials, or before there can be public dissemination of techniques, there must be enough productive basic research to provide the fundamental science from which these efforts flow".

It appears that the current administration shares this view but it reminds us, with increasing frequency, that the resources which have been available to support the nation's biomedical research efforts are unlikely to expand. It is even probable that they will decline as an aftermath of Proposition 13.

Basic research is a quest for new knowledge and understanding, an exploration of the unknown wherever it may lead. In the words of Secretary Califano: "There must be freedom to pursue research topics that are not immediately relevant, for basic research is nothing less than a long-term investment and one cannot program or order neatly the mysterious and serendipitous ways in which new knowledge is developed"(1). I must recall at this point that new knowledge and understanding is the sine qua non of all significant advances in the conquest of disease and the maintainence of health.

If the discovery of new knowledge and the acquisition of new insights cannot be preprogrammed or directed and if their application or relevance to the solution of urgent health problems cannot be predicted, how then can limited resources be rationally allocated to support basic research? I believe that such an allocation must be mandated on some formula basis lest the goose that lays the golden egg be consumed by the claims of more immediate and undeniable needs.

By recent accounting 28% of the total NIH R & D budget has been allocated to basic research, down from 38% in the mid-1960's (2). I suggest that a proportion of this magnitude, say no less than 40% of all funds appropriated or assigned to categorical institutes, divisions, commissions and programs, be automatically obligated for the funding of basic research. A form of basic research overhead, if you will.

Because the only predictable outcome of a basic research effort is that it will come to naught unless it is pursued by good scientists, I further propose that this basic research overhead be pooled and allocated to investigator-initiated research projects solely on the basis of scientific merit as judged by peer review.

Such a mechanism will ensure, over time, the construction of a suitable science base for application to specific health problems, will depoliticize the funding of basic research and provide continuity and stability of support in the face of changing passions in the health arena, an absolute requirement for the viability of the scientific enterprise.

(1) Address to Annual Meeting of the American Federation for Clinical Research, San Francisco, April 28, 1978.

(2) Basic Research in the Mission Agencies. Report of the National Science Board, National Science Foundation, 1978.

Mr. Chairman, Distinguished Members of the Committee:

My name is Douglas Astolfi, and I am a member of the Board of Directors of the American Brittle Bones Society; a society dedicated to stimulating and and supporting research into cause, cure, and treatment of Osteo Genesis Imperfecta, Osteoperosis and related bone diseases.

Osteoperosis is a well known degnerative bone disorder. Osteo Genesis Imperfecta is a disease of the connective tissue presenting numerous fractures with minimal trauma, severe muscle sprains, defective teeth, dwarfism, deafness and heat sensitivity among other complications.

The American Brittle Bones Society wishes to take this opportunity to thank Mr. Califano, his staff, and members of the N.I.H. staff who have made this conference possible. We believe that a conference dedicated to the issues of health research principles and to setting the goals and priorities for such research is most important. While we, of course, would like to expand upon some of the priorities that have established, we basically support the underlying priorities enumerated in the attachments to Mr. Califano's September 15th memo.

Specifically, we would like to take this opportunity to emphasize and modify four points. First, in Attachment Three, page 3, the memo states that "expanded support for multi-year, high cost clinical applications and health services research activities should be in addition to, not in lieu of, support for fundamental research." We agree with the principle stated here. However, we are concerned that in taking such an inclusive look at research, there may be a tendency to spread funding equally.

We applaud efforts to educate the public concerning health hazards but we believe that the fundamental answer to our national health care needs can only be found in basic medical research. Any diminution of funds available for such research is, in the long run, neither efficacious nor cost efficient.

Second, on the same page, paragraph 5, states that "support for the application of proven new knowledge and technology is available from multiple sources." We wish to encourage NIH and DHEW staff to take the availability of such funds into account when allocating the federal research dollars. In other words, the American Brittle Bones Society supports the principle that federal dollars be expended for research in dideases especially when no non-federal support is available for such research.

Third, attachment two, page 26, paragraph 2, states that "burden of illness measures, demographic funds, (and) public perception of relative importance of different health areas ..." should be factors in determining priorities for federal expenditures. First, both burden of illness measures and demographic trends are imperfect statistical measures. As both Mrs. Dorothy Rice, Director, National Center for Health Statistics and Dr. Gerald Rosenthal, Director, National Center for Health Services Research, pointed out in their addresses to the September 21, 1978, National Arthritis Advisory Board Forum on Public Policy and Chronic Disease, such measures are products of imperfect data collection. For example, as there is no national patient register of Osteo Genesis Imperfecta patients, researchers do not even know how many people are affected by this disease.

Secondly, we believe that "public perception" should never be a measure for determining the allocation of research funds. Using "public perception" can only turn such allocations into disease of the month popularity contests where determination of funding will no longer be governed by the scientific merit of a proposal but by the level of popular support such funding might generate.

Finally, the American Brittle Bones Society respectfully suggests the inclusion of one more item for consideration. We believe that every effort should be made to stimulate research in areas which have been neglected in the past. Those areas which have received little or no research support should be reopened and every effort should be made to stimulate researchers to examine disease and related health issues which have been ignored. Osteo Genesis Imperfecta is not the only bone disease that has suffered from a lack of research attention and funding. In general, virtually all hereditary and degenerative bone diseases have tended to be ignored in the distribution of federal research dollars.

We strongly urge that federal dollars be allocated to research in these neglected areas.

Thank you for affording us this opportunity.

THE LIVING BANK Lorraine Gress, Executive Dire
P.O. Box 6725
Houston, Texas 77005 713-528-2971

UNIFYING CONCEPTS

October 3-4, 1978

The following position paper of The Living Bank is submitted as part of the HEW Conference on multi-year strategy for support for health research:

1. PURPOSE
The Living Bank is a non-profit service organization dedicated to helping those persons who, after death, wish to donate a part or all parts of their bodies for the purposes of transplantation, therapy, medical research, or anatomical studies. It was chartered as a Texas corporation August 9, 1968.

2. ACTIVITIES

A. Education
In an effort to educate the public that being a donor should be the usual rather than the unusual thing, The Living Bank fulfills public speaking engagements before religious, civic and community groups and assists in courses on death and dying. Publicity, both local and national, through newspapers, magazines, radio and television, generates thousands of inquiries each year.

B. Registration
The Living Bank has responded to more than 600,000 telephone and mail requests for information. When such a request is received, a brochure is sent explaining the donor program, together with a donor form and a donor card. The inquirer may then complete the legal documents and return the donor form for processing and registration.

C. Referral
The Living Bank maintains a 24-hour telephone referral service in order to make timely referral of donations to medical schools, eye banks, kidney transplant facilities and other organ banks in every state of the union. There is only a limited time following the death of a donor in which to harvest the organs, i.e.:

vital organs (kidneys, hearts, lungs) -- 20 minutes
corneas -- 4 hours
skin -- 18 hours

It is therefore necessary for prompt referral that a current directory of telephone numbers, institutional procedures, and names of personnel for all appropriate medical facilities be maintained. Our records reveal that 91.5% of organ and body donations of members of The Living Bank are utilized, primarily due to our 24-hour referral capability. The remaining 8.5% are rejected for medical reasons.

3. JUSTIFICATION OF NEED

Our country has some of the most outstanding medical centers in the world, where life-saving kidney transplants are being performed; corneal transplants are bringing sight to many blind persons, and other organ and tissue transplants are aiding in the treatment of the severely burned, bone cancer, deaf ... the list is endless! THE SHOCKING FACT IS, HOWEVER, THAT MANY OF THESE TRANSPLANT AND RESEARCH PROGRAMS ARE SEVERELY HANDICAPPED BY THE SHORTAGE OF ORGAN AND BODY DONATIONS.

An essential resource to medical research is a sufficient supply of human materials to enable present transplant or tissue utilization programs to continue, as well as to serve the breakthroughs on the horizon which will bring hope to many persons suffering from diabetis, cancer, and the like.

4. FACTS CONCERNING PRESENT ORGAN DONATION PROGRAMS

A. The American Medical Association issues uniform anatomical gift cards. Most medical schools have their own willed body programs. Organ donor programs, in conjunction with the issuance of driver's licenses, exist in most states.

B. Specific groups provide educational information concerning their particular program (i.e., kidney foundations, eye banks, The Deafness Research Foundation, skin transplant centers, The National Pituitary Agency, etc.), and often this material includes a donor card for that program only.

C. The Living Bank is not a medical organization, but rather a humanitarian endeavor serving all programs in need of organ donations by referring the donor's gifts to the specific medical organizations for utilization.

D. Persons making the commitment to be a donor are a very special kind of people, with deep concern for others. Therefore, it is importent that the offer of such a donation be handled sensitively at the time of death. It is pointless to educate people to be donors if their gifts are not utilized, or if it results in confusion and frustration for the grieving family in attempting to carry out the wishes of their loved one

E. Much to our astonishment, we have discovered repeatedly that hospital and emergency services personnel (ambulance, police, etc.) lack adequate information for proper handling and timely referral of such donations.

5. RECOMMENDATIONS

A. Education must include not only the public, but those coming in contact with the donor so that proper handling and timely referral will enable the utilization of such donations. This includes hospital administration, nursing staff, physicians and surgeons, ambulance staff, police officers, firemen, paramedics, and other emergency service units, as well as morticians. This could partially be addressed through continuing education programs in hospitals and universities. The educational process should encompass the various medical groups requiring organ or body donations, and their specific requirements. It would require continual updating in order to keep current with medical research and advancements. Money needs to be allocated for this comprehensive education.

B. Registration. At the present time people carry many forms of donor cards. To our knowledge, 47 states have some form of organ donor program associated with their driver's licenses. The majority of the cards do not carry a 24-hour telephone number where assistance can be offered in making timely referral. An organ donor registry which contains appropriate data concerning all organ donors needs to be established and maintained. This could either operate at the state level or feed into one national registry. Funds need to be allocated for the research and methodology of establishing such a registry, and then the actual development of same. This would require advertising and promotion in order to reach all persons presently carrying some form of donor card. The data should then be fed into a computer system for purposes of recordation and retrieval. This would require a substantial investment in the beginning and continuing maintenance funds.

C. Referral. The registry referred to above should also contain current data on all programs requiring human material throughout the United States, including statement of need, handling instructions, carrier, and other pertinent information necessary for effective referral of donations at time of death. This would require constant update. An emergency WATS number should be assigned to this program.

D. It is essential that funding be made available to develop a comprehensive organ donor program to serve the medical research needs not only of today, but for the foreseeable future.

5. RECOMMENDATIONS (continued)

The Living Bank is uniquely qualified to research and develop such a program. This is borne out by several factors:

- It serves all groups and organizations, rather than being limited to only one area of medical concern.
- It is the most widely known and recognized program throughout the United States which encompasses both organ and body donor programs.
- It receives regular national attention via newspapers, magazines, television and radio.
- It has a current membership of approximately 100,000 card carrying donors, and new members are being added by the thousands each month.
- Its record of 91.5% utilization of referred donations attests to the successful operation of its program.

Organ and body donation is considered a "voluntary giving of oneself to others." There is no remuneration associated with such a gift. The only payment is in the satisfaction of knowing this gift has been offered during one's lifetime. Therefore, it is even more important that adequate programs be funded to allow this process to occur effectively and in an orderly and sensitive manner.

Submitted by:

Lorraine V. Gress
Executive Director

Date:

October 3, 1978

Charles A. Kiesler
Executive Officer
American Psychological Association

Panel: Unifying Concepts

I am pleased to be here today to discuss ways to develop a stable health research policy. I would like to use the brief time allotted to emphasize the relationship of psychology and the behavioral sciences to health research policy. This is a very complex area but I will try to be as brief as I can.

First, I suggest that a broad policy is inherently more stable than a narrowly stated one. There are peaks and valleys in the accumulation of knowledge within any discipline and a broadly stated policy can better ensure steady scientific progress across a variety of disciplines. A preliminary question is, What does "health" mean?, in health research policy. The broadest definition is that endorsed by the World Health Organization (WHO): "Health is a state of complete physical, mental, and social well-being and not merely absence of disease and infirmity."

Research on health, at least as defined by WHO, would include as an integral component basic and applied work in psychology and the behavioral sciences. Of course, the relationship between behavioral and biomedical research is very complicated and inadequately understood. However, it is clear that behavioral research is critical for a complete understanding of health and should be incorporated into planning from the initial stages. Research in areas closely related to the overlap of biomedical and behavioral topics is burgeoning. A new division of APA on health psychology was recently initiated with over 700 new members, for example.

Behavioral research in health is currently going on in widely divergent areas. It includes study of behavioral components underlying susceptibility to medical conditions such as the relationship between stress and certain cardiac conditions, and psychological factors related to the onset of diabetes, cancer and epilepsy. Behavioral techniques are widely used in treatment of such conditions as autism, bruxism and obseity. Indeed Logan Wright estimates that between one-third and one-half of patients in his children's hospital have a highly significant behavioral concomitant to their physical illness, aside from the emotional problems caused by the hospitalization itself.

However, HEW needs to support and encourage basic research in the behavioral sciences far beyond their assumed relationship to health. Let me give only two quick examples. Behavior modification has become a technique, or a technology if you will, that is successfully applied in areas ranging from obesity to tracheotomy addiction. Its relationship to biomedical research is somewhat obvious now and support for further study could easily be justified. But our knowledge of behavior modification depends upon a sequence of scientific work on learning that goes directly back to such scientists as Watson and Thorndike in the early part of this century. I urge that HEW define its health research policy such that such basic work would be actively encouraged.

Another example. An important problem in medicine these days is that of medical compliance, such as taking drugs as prescribed or following medical regimens. It has been estimated that the costs of lack of medical compliance run as high as 30 billion dollars a year for the U.S. alone. There are a variety of models of behavioral and attitudinal change that could easily be applied with great savings in this area. Compliance falls under the broad rubric of health research, but again the underpinning basic research in social psychology and sociology has been going on the 30 years and researchers have largely had to seek their basic funds outside HEW.

Parenthetically, psychology and the behavioral sciences need some nurturance in an overall policy statement. Funding in these areas has been less stable than in either the biomedical or physical sciences. I can speak most easily of funding in psychology. Over 11 percent of doctoral level scientists in the U.S. are psychologists. They receive approximately 1.5 percent of the total federal funds for basic research. During the period of Fiscal Years 1972-76, a time of great pressure on the financial commitment to science in general, the proportion of funds going to psychology dropped by one-third. During that time the proportion of federal funds for basic research going to the biological sciences increased.

Let me suggest some recommendations for HEW for its health research policy:

1. Define health in its broadest sense.
2. Include varieties of psychological and behavioral science research explicitly among priorities.
3. Track the financial contributions to behavioral science better and attempt to evaluate its current and potential contributions.
4. Support basic research in the behavioral sciences more generally, and not simply the most immediate application of current knowledge developed over a long period of time.

THE AMERICAN COLLEGE OF PHYSICIANS

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EDITOR

Presentation Before the N.I.H. Conference on Health Research Principles
NIH Campus
Bethesda, MD
October 3-4, 1978
By Dr. Ceylon Lewis

INTRODUCTION

I am Dr. Ceylon Lewis, Chairman of the Board of Governors of the American College of Physicians. On behalf of the entire College of 40,000 and more members, I wish to congratulate the department, its secretary and the director of the National Institutes of Health, Dr. Donald Fredrickson for the undertaking of this national conference on health research principles. We appreciate the opportunity to assist the department in developing health research principles for the coming years. Developing health research principles is a very serious and critical activity to insure that the American people continue to receive the highest quality of care in the world.

THE AMERICAN COLLEGE OF PHYSICIANS

The American College of Physicians was formed in 1915 specifically for the purpose of maintaining and advancing the highest possible standards in medical education, medical practice and research. (For the purpose of this conference I wish to emphasize the medical research.) In the coming years, it may be anticipated that important discoveries in biology, chemistry and physics will continue to come from our research laboratories. It is the preservation of this noble process that comes under discussion today.

In the early 1960's a Master and Past President of the ACP, Dr. Hugh Butt of the Mayo Clinic, stated that "to understand the proper allocation of this knowledge to the prevention and cure of disease in man will require physicians who have both broad and long training in biology and medical science. These physicians must understand the normal and abnormal biological differences between men, their emotional responses to multiple situations, and their body responses to inherited or acquired disease".[1.]

The current president of our American College of Physicians, Dr. Jeremiah A. Barondess, recently commented about the elements of the medical profession lineage which "include the questioning of current opinion in the search for new formulations; the framing of clinical and physiological hypotheses on the basis of careful clinical observation; and pursuit of a sense of clinicianship based on biologic science".[2.] If U.S. medicine is to continue to reflect high quality, every physician and clinical-investigator must maintain the traditional monentum of motivation and intellectual curiosity that has epitomized medicine in the modern era. To wonder, to observe, and to contribute is the essence of the physician and the clinical-investigator.

THE CLINICAL INVESTIGATOR - AN ENDANGERED SPECIES

But the clinical investigator and clinical investigator-teacher are endangered species. As Thomas W. Burns, M.D., F.A.C.P., University of Missouri, stated as recently as last week, a decline in interest and funding "could have significant consequences on biomedical research, medical education and health care in general".[3.]

In 1975, and as a result of public law 93-348, the Committee on a Study of National Needs for Biomedical and Behavioral Research

Personnel was established. With a membership consisting of physicians and other individuals representing other disparate disciplines, the Committee addressed health manpower related research needs and the requisite funding for the education of the needed manpower.

Public law 93-348 also required this Committee to annually report its findings and recommendations. The Committee's 250 page 1977 report addressed manpower and training issues in several areas, including basic biomedical, behavioral, clinical sciences and health services. Several critical problems were highlighted in the 1977 report and they are as true today as then.

DISINCENTIVES FOR CLINICAL INVESTIGATION

There are several financial disincentives in career clinical investigation. The usual research stipend is less than the income that can be earned in beginning private practice and even in residency training, thus there is no financial incentive to become a clinical investigator. Although the situation is improving, in general, academic physicians earn considerably less in their lifetime than the practicing physicians. In the past, intellectual rewards more than compensated, but this inclination seems to be declining.

Substantiating data to support these statements includes the fact that from 1971 to 1975, the number of physicians who indicated that their primary activity was research, decreased at an annual rate of 7%. AMA data shows this alarming decrease. Approximately 3% to 4%, of medical students choose academic medicine as their primary activity. The percentage of first time investigators who are physicians is declining.

The amount of money appropriated for research development to medical schools has increased at a rate less than the increase of medical school enrollments. The Committee on a Study for National Needs for Biomedical and Behavorial Research Personnel pinpointed the growing need for clinical faculty. But with clinical faculty becoming more involved in patient care activities, clinical investigation is attracting a smaller percentage of clinic faculty.

As those in NIH already know, in 1968-1973, there were increasingly unfilled, yet budgeted, positions in many departments of medicine in the United States. There is a definite need for increase in the awards made for traineeships and fellowships. NIH presently supplies only 15% of stipend support for Fellows. NIH should increase this percentage. Training in the clinical sciences should be encouraged aggressively by NIH.

CONCLUSION

Thus, the American College of Physicians feels very strongly about the two fold purpose of this conference: 1) research capability, and 2) clinical applications and health services research. We must assure as a nation that the people and dollars, necessary for the continued support of clinical research are available. NIH should be a major provider in this activity. The continuous development of knowledge to support the medical and health care function is critical, just as it is essential to apply the new knowledge. If research slows, the impact on quality of clinical care will not be felt for many years. It is an insidious process. But in time the decreased flow in the pipeline will be felt. The imput at the research end must be preserved, or soon we will be "delivering" stagnent health care.

The 40,000 plus doctors, primarily internists, who are members of the American College of Physicians, have often been described as the physicians to the inner man, the whole man. In line with the fifth major focus of this conference, mainly unifying concepts, the ACP reflects medicine in its interdependent concerns with patient care, medical education, and research. The vitality of medicine arises from the well spring of new knowledge.

We are here to reaffirm the need for strong and increased federal support of fundamental and applied health research. We know the need for the bridges between fundamental and applied research. This is what the ACP represents. We are here to offer our help and assistance in the public-private cooperative interactions and processes as symbolized in this most significant conference.

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October 2, 1978

Honorable Joseph A. Califano, Jr.
Secretary of Health, Education
and Welfare
Washington, D.C. 20201

Dear Mr. Secretary:

Basic health research is important to the well being of our people. It should be supported by the government --- not with limited dollars, but with adequate dollars.

This support should be provided on a multi-year basis. Scrounging annually for the research dollar does not contribute to scientific knowledge. Hit and run funding does not work for the long pull.

Shifts in funding and research emphasis should not be abrupt since much time is needed to acquire expertise in any scientific area. Frequent shifts only benefit the dabbler who can switch his ignorance from one disease to another with great facility.

Still, all scientists whose research is funded by the people's money must be held accountable to the people. Peer review is fine but is not enough. The people have a right to know how their money is spent. Progress reports in plain English would be helpful. Gobbledygook and sensational claims would not. Half-baked theories heatedly arrived at may be dangerous to our health.

Funds should be allocated on the basis of priorities. Morbidity and mortality rates should help determine those priorities. Government should pursue a more rational policy than our voluntary health agencies. Emotions, celebrities, slogans and headlines should not be permitted to institutionalize a disease-of-the-month club at N.I.H. Let's keep politicians from the temptation of warring on this or that disease. Let's remember that research is plodding inquiry highlighted by occasional revelation.

Where most of the answers are in, the immediate payoff should be given the highest priority. Getting drunk drivers off our roads would save many lives and immunization against measles would prevent many costly complications.

There need be no conflict between high technology medical diagnosis and humane treatment. It is only when diagnosis is unclear and treatment uncertain, that the patient is studied like a bug under a microscope and handled like a slab of meat. Therefore, funds spent on research can payoff in improved clinical care by a) increasing cure rates, b) avoiding unnecessary interventions, c) reducing anxiety and d) lowering costs.

More attention should be paid to the funding of unconventional projects. Health-and-nutrition and Dr. Linus Pauling come immediately to mind.

And while nobody wants to get Senator Proxmire's Golden Fleece Award, neither should it get in our way.

One must welcome the encouragement of young scientists, but this should not be done at the expense of older, more experienced researchers. I still don't buy the assumption that every person under 30 has an open mind, and that every person over 70 has reached a dead end.

Still, I think less emphasis should be placed on extending life for a few more years and more stress should be placed on diet and preventive medicine to permit the full potential of the fetus to be realized during the adult years.

I hope my fellow trade unionists in the paper industry will forgive me, but something must be done to free the scientist from oppressive paperwork. There should be a reduction in the requirement of forms as well as employment of clerks on smaller projects which often are required to produce as much paperwork as the larger ones.

Mr. Secretary, you are on the right track.

Sincerely,

Leo

Leo Perlis, Director
Department of Community Services

LP:mm

CC: Dr. Donald Fredrickson

I AM PEYTON E. WEARY, M.D., CHAIRMAN OF THE DEPARTMENT OF DERMATOLOGY AT THE UNIVERSITY OF VIRGINIA SCHOOL OF MEDICINE. I APPRECIATE THE OPPORTUNITY TO PRESENT THESE RECOMMENDATIONS ON BEHALF OF THE SOCIETY FOR INVESTIGATIVE DERMATOLOGY.

PREAMBLE:

THERE APPEARS TO BE SUBSTANTIAL AGREEMENT ON THE FOLLOWING POINTS:

1. INCREASED STABILITY OF FUNDING FOR BIOMEDICAL AND BEHAVIORAL RESEARCH ON A RATIONAL BASIS IS HIGHLY DESIRABLE.
2. RE-ESTABLISHMENT OF PRIORITIES TO PROVIDE MORE APPROPRIATE LEVELS OF SUPPORT FOR THOSE RESEARCH ACTIVITIES WHICH ARE MOST COST EFFECTIVE IN TERMS OF REDUCING THE ECONOMIC BURDEN OF ILLNESS, INCREASING THE PRODUCTIVITY OF SOCIETY AND PREVENTING DISEASE SHOULD BE STRONGLY CONSIDERED.
3. FINANCIAL SUPPORT FOR THE EXPLOITATION OF SCIENTIFIC OPPORTUNITY AT ALL LEVELS AND IN ALL DISCIPLINES SHOULD BE READILY AVAILABLE.
4. INCREASED PARTICIPATION OF VOLUNTARY HEALTH AGENCIES AND THE PRIVATE SECTOR IN THE SUPPORT FOR RESEARCH SHOULD BE ENCOURAGED.

WE BELIEVE THE FOLLOWING THREE RECOMMENDATIONS EFFECTIVELY ADDRESS ALL OF THESE ISSUES:

1. TO ENHANCE THE STABILITY OF RESEARCH FUNDING AND TO RE-ESTABLISH ALLOCATIVE PRIORITIES ON A RATIONAL BASIS;

WE RECOMMEND

THAT THE TOTAL YEARLY MINIMUM LEVEL OF SUPPORT FOR BIOMEDICAL

AND BEHAVIORAL RESEARCH CONDUCTED UNDER THE AUSPICES OF THE NATIONAL INSTITUTES OF HEALTH AND THE ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION SHOULD BE ESTABLISHED AS A FIXED PERCENTAGE OF THE TOTAL ECONOMIC BURDEN OF ILLNESS. THE TOTAL ECONOMIC BURDEN OF ILLNESS SHOULD BE DEFINED AS BOTH THE DIRECT HEALTH CARE COSTS TO SOCIETY AND INDIRECT COSTS OR LOSSES ESTIMATED TO RESULT FROM MORBIDITY, MORTALITY AND REDUCED PRODUCTIVITY BY THE NATIONAL CENTER FOR HEALTH STATISTICS. THE REFERENCE YEAR FOR EACH ANNUAL APPROPRIATION SHOULD BE THE MOST RECENT YEAR FOR WHICH SUCH DATA AND ESTIMATES CAN BE DEVELOPED AND WOULD PROBABLY BE TWO YEARS PRIOR TO THE APPROPRIATION YEAR. A REASONABLE PERCENTAGE FIGURE WOULD BE IN THE NEIGHBORHOOD OF 2% OF THE AGGREGATE (DIRECT AND INDIRECT) COSTS. TO THIS MINIMUM LEVEL OF SUPPORT THE CONGRESS MAY WISH TO ADD ADDITIONAL SUMS FOR HIGH PRIORITY AREAS WHERE ECONOMIC LOSSES TO SOCIETY SUGGEST THE NEED FOR EXTRA EFFORT.

THE RATIONALE FOR RELATING RESEARCH EXPENDITURES TO THE ECONOMIC BURDEN OF ILLNESS IS CAREFULLY DOCUMENTED IN A PAPER BY RICE, FELDMAN AND WHITE ENTITLED, "THE CURRENT BURDEN OF ILLNESS IN THE UNITED STATES", PREPARED FOR THE INSTITUTE OF MEDICINE. THE IMBALANCES WHICH HAVE RESULTED FROM INATTENTION TO ECONOMIC ISSUES IN THE ALLOCATION OF FUNDS ARE HIGHLIGHTED BY THIS PAPER AND IT IS OBVIOUS THAT THE OVEREMPHASIS ON RESEARCH FOR SELECTED FATAL DISEASES HAS BEEN AT THE EXPENSE OF RESEARCH IN MANY OTHER AREAS WHERE ACUTE AND CHRONIC NON-FATAL ILLNESS CRIPPLE, IMPAIR THE PRODUCTIVITY OF SOCIETY AND REDUCE THE QUALITY OF LIFE.

2. TO STIMULATE THE EXPLOITATION OF SCIENTIFIC OPPORTUNITY AND NEW INITIATIVES:

WE RECOMMEND

THAT, IN ORDER TO CREATE A GREATER FLEXIBILITY IN THE ALLOCATION OF FUNDS FOR BIOMEDICAL AND BEHAVIORAL RESEARCH, AT LEAST 5% OF THE FUNDS APPROPRIATED YEARLY FOR THE NATIONAL INSTITUTES OF HEALTH AND THE ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION BE DISCRETIONARY, I.E. NOT ALLOCATED TO A SPECIFIC INSTITUTE OR ORGANIZATIONAL COMPONENT. THESE DISCRETIONARY FUNDS SHOULD BE PLACED AT THE DISPOSAL OF A NATIONAL RESEARCH FUNDING PANEL COMPOSED OF KNOWLEDGEABLE AND BROADLY REPRESENTATIVE INDIVIDUALS TO BE DISTRIBUTED ACCORDING TO PERCEIVED NEEDS AND PRIORITIES FOR THE FOLLOWING PURPOSES:

A.) TO SUPPORT PROMISING NEW SCIENTIFIC OPPORTUNITIES WHERE FUNDS ARE LIMITED

B.) TO STIMULATE NEW RESEARCH IN PRIORITY AREAS NEGLECTED BY CONGRESSIONAL MANDATES

C.) TO PROMOTE THE DEVELOPMENT OF RESEARCH MANPOWER IN DESIRABLE PROGRAMATIC AREAS

D.) TO ENHANCE APPROPRIATE TECHNOLOGY TRANSFER AND THE INTERDISCIPLINARY DISSEMINATION OF NEW KNOWLEDGE

E.) TO ENCOURAGE PROGRAMS WHICH STRESS DISEASE PREVENTION CONSISTENT WITH THE RESEARCH OBJECTIVES

3. TO PROMOTE INCREASED RESEARCH SUPPORT FROM VOLUNTARY HEALTH AGENCIES;

WE RECOMMEND

THAT THE CONGRESS ANNUALLY APPROPRIATE FUNDS SUFFICIENT TO MATCH ON AT LEAST A DOLLAR-FOR-DOLLAR BASIS THOSE FUNDS CONTRIBUTED

BY LEGITIMATE VOLUNTARY HEALTH AGENCIES AND PHILANTHROPIC FOUNDATIONS TO THE SUPPORT OF BIOMEDICAL AND BEHAVIORAL RESEARCH FOR SELECTED DISEASES OR CATEGORIES OF DISEASES DURING THE PRECEDING YEAR. THESE MATCHING FUNDS SHOULD BE PROVIDED ONLY TO MATCH THOSE FUNDS DIRECTLY CONTRIBUTED TO BONA FIDE RESEARCH BY LEGITIMATE ELEEMOSYNARY ORGANIZATIONS. THE MATCHING FUNDS WOULD BE GRANTED TO A SPECIFIC INSTITUTE OR COMPONENT OF EITHER THE NATIONAL INSTITUTES OF HEALTH OR THE ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION AS RECOMMENDED BY THE VOLUNTARY HEALTH AGENCY OR FOUNDATION AND NOT TO THE AGENCY OR FOUNDATION PER SE. TO ASSURE APPROPRIATE DISTRIBUTION OF FUNDS AND THE QUALIFICATIONS OF THE AGENCIES TO REQUEST SUCH FUNDS, THIS PROGRAM SHOULD BE UNDER THE DIRECTION OF THE NATIONAL RESEARCH FUNDING PANEL.

THIS NEW INITIATIVE WOULD OFFER FOUR POSITIVE BENEFITS:

A.) IT WOULD STIMULATE INCREASED PRIVATE SECTOR SUPPORT FOR BIOMEDICAL AND BEHAVIORAL RESEARCH

B.) THOSE DISEASES WHICH MOST CONCERN SOCIETY WOULD RECEIVE THE MOST SUPPORT

C.) PROPORTIONATELY MORE RESPONSIBILITY FOR CATEGORICAL RESEARCH SUPPORT WOULD FALL UPON PRECISELY THOSE INDIVIDUALS WHO STAND TO GAIN MOST FROM SUCH RESEARCH

D.) A MECHANISM WOULD BE CREATED TO ENSURE APPROPRIATE LEVELS OF PUBLIC SECTOR SUPPORT FOR CATEGORICAL RESEARCH OF GREAT CONCERN TO PRIVATE SECTOR AGENCIES

THANK YOU FOR THE OPPORTUNITY TO PRESENT THESE RECOMMENDATIONS.

Panel: Unifying Concepts

Testimony of

Martin D. Kamen, Ph.D., Sc.D.,

Professor Biological Sciences,
University of Southern California
and Emeritus Professor of Biochemistry,
University of California at San Diego.

In this short format, my remarks must be general and addressed to but a few of the areas of inquiry which concern this Panel. I will comment on just two major problems in this effort to construct a sound National support policy in the Health Sciences.

The first is the need to recognize that a qualitative difference exists between biological research which is conceptually oriented and deals with the discovery of, and refinement of, basic biological principles, and research which is essentially mission-oriented. It has been traditional in our society to emphasize the latter as "practical" and the former as "long-haired". Our continued survival requires a change in this attitude. It must be understood, as has been the case in other societies of the Western World, that investment in fundamental research is necessary, even though not immediately practical, because without it stagnation and decay are inevitable. The small body of individuals gifted with the creativity and insight to carry forward this endeavor is a natural resource that must be maintained, whatever the cost. Fortunately, the cost does not appear to be significant. We may have a short-range solution in the simple procedure of increasing the budget allotted to the one Concerned Institute which now exists in NIH -- that of the General Medical Sciences. This Institute, created in response to the realization some means was required to assure performance of non-mission oriented research in the Health Sciences, has never been funded to serve adequately the crucial needs which exist. This Panel should inquire as to what sum in actuality would remove the current problems of malaise and demoralization in the predoctoral and post-doctoral training effort. My impression is that so "drastic" an approach as doubling the current budget, in terms of inflation dollars, would make no appreciable dent in NIH expenditures while it would go far in the short range to restore the momentum of the nation's creative effort in the Health Sciences, which federal funding made possible in the post-sputnik era. When statements are made that cuts must be made in all areas of Health Science funding, it is not appreciated that the resultant effect on basic research is disproportionately great, because of its small magnitude in personnel and material, compared to the relatively gigantic sums and allocation of personnel and materials associated with contract mission-oriented projects in the clinical and environmental science areas. To make an analogy, this approach is like demanding a proportional cut in size of all organs in a person who is overweight. Some organs, like the brain and heart, cannot be tampered with in this way.

The second problem area is the means whereby the electorate can be educated to understand the scientific endeavor -- what science is, how it works and what are its limitations. In particular, the public and especially its electoral representatives need to know how the present Federal machinery for Health Science support functions so that they can help approach in a sound manner ways to improve its performance. This is a long-range effort and requires thought on the part of this Panel, which is charged with inquiry into unification of managerial and support concepts in nationwide planning of Health Science support policy. I might suggest that a Head-Start kind of program is needed, beginning with instruction in high school on the philosophy of the scientific method, while including much practical instruction as to current legislation and constitutional organization in the NIH. It is crucial that there be an informed public responsive to national needs in training and research effort at the basic levels in the Natural Sciences. Only then can adequate support be achieved in formulation and implementation of funding, which is not subject to wild oscillations and resultant instability, in planning of the long-range effort characteristic of basic research in the Health Sciences.

Major rewards in great savings of public monies will be made with success in this endeavor to create a sound National Science Policy assuring a healthy program in basic biological science. As an example, there is a real danger in squandering of public funds-in efforts to minimize environmental threats to health—based on inadequate data, or unproven concepts, in addition to the danger of unwarranted interference with research in crucial areas for continued progress in our understanding of biological processes. The recent controversy on regulation of recombinant DNA research is still fresh in our minds. Another tortured area is the regulation of dosage in pharmaceuticals. In these and many other problem areas, there is a temptation to run ahead of hard knowledge in passage of legislation, that is, do something rather than nothing. The fact this situation exists is adequate basis for the plea that we still need more basic research, rather than less.

SUMMARY OF RECOMMENDATIONS MADE BY FRANK E. YOUNG, M.D., Ph.D., PROFESSOR AND CHAIRMAN, DEPARTMENT OF MICROBIOLOGY, UNIVERSITY OF ROCHESTER, MICROBIOLOGIST-IN-CHIEF, STRONG MEMORIAL HOSPITAL, ON BEHALF OF THE AMERICAN SOCIETY FOR MICROBIOLOGY, TO THE PANEL ON UNIFYING PRINCIPLES

1. We recommend maintenance of a dynamic partnership between the federal government and private sector in research and research training.

2. We recommend maintenance of high-quality research throughout the continuum of activities: basic research, applied research, and mission-oriented research. Flexibility must exist for new initiatives when problems arise that need research efforts, such as the epidemic of sexually-transmitted diseases and Legionnaire's Disease. Furthermore, peer-reviewed research in health care delivery should be undertakern to maximize the efficiency of our health care delivery system.

3. We recommend a multi-disciplinary analysis of the utilization of our health system with particular attention on teriary care.

4. Research efforts on prevention of disease are the bedrock of an effective health care system. Therefore, maximum attention should be given to those aspects of our research and research training that lead to the discovery of the causes and prevention of disease.

5. We recommend increased efforts in communication between health professionals and the public to ensure efficient utilization of the health care system and to communicate realistic expectations of research and treatment.

6. We recommend maintenance of centers of excellence in health research and health research training. The cost of education, including the renovation of obsolete physical plants, must be realized and provided for.

7. We recommend that the federal government set standards of excellence

by example and not merely by regulations.

8. We urge coordination and reorganization of the federal health resources so that the pluralistic approach is articulated and not disjointed.

TESTIMONY OF FRANK E. YOUNG, M.D., Ph.D., PROFESSOR AND CHAIRMAN, DEPARTMENT OF MICROBIOLOGY, UNIVERSITY OF ROCHESTER, MICROBIOLOGIST-IN-CHIEF, STRONG MEMORIAL HOSPITAL, ON BEHALF OF THE AMERICAN SOCIETY FOR MICROBIOLOGY, BEFORE THE PANEL ON UNIFYING PRINCIPLES

I am Frank E. Young, M.D., Ph.D., Professor and Chairman of the Department of Microbiology, University of Rochester, and Microbiologist-in-Chief at the Strong Memorial Hospital. I am testifying today on behalf of the American Society for Microbiology, which is composed of over 29,000 members who contribute to such applied fields as those of infectious desease and clinical microbiology, as well as such fundamental areas as immunology, pathology, genetics, virology, and oncology. We are pleased to have this opportunity to address some of the principles that determine the unifying concepts for health research.

First, we wholeheartedly endorse the maintenance of a dynamic partnership between the federal and private sectors in health research. Because research and research training provide national resources that know no state border, it is appropriate that the federal government take the lead in providing a stable environment in which research and research training can flourish. Biomedical science is a national resource.

Second, research is a broad spectrum, a continuum of activities. It is difficult to clearly separate basic, applied, and mission-oriented research. While our research efforts were extremely strong up until the early seventies, it is now widely recognized that these capacities have diminished, in part due to decreased levels of support, erratic funding, and obsolete facilities. Prompt redress should be instituted with particular attention on investigator-initiated research. At the same time, flexible and non-competing funds must be available for new initiatives, such as the program on sexually-transmitted diseases and the research activities on Legionnaire's Disease. The physical suffering, emotional trauma, and economic chaos that was observed in Philadelphia during that outbreak must be prevented through well-designed research programs. Furthermore, the changing needs of our population should be met through increased research in vital areas, such as the process of aging. Finally, we recommend that a careful peer-reviewed research program in health care delivery be mounted to maximize the efficiency of our health care system.

Third, we recommend that broad consideration be given to the social biology of illness, dying, and death. In our high technologically-oriented society, it is possible to prolong life. The 1978-1982 forward plan for health attempted to analyze the cost-effectiveness of treating various illnesses in terms of years of productivity. This plan noted, "We have gradually shifted to a pattern in which more highly trained specialists are utilizing additional and more sophisticated health services, equipment, and devices. As a result, although our ability to diagnose, treat, and manage acute and chronic problems is far better now than it has ever been, a higher price is being paid for the resulting improvement of health care." Therefore, we support a careful analysis of types of technology that should be applied to the maintenance of life and the types of personnel that should be trained to augment the health system. Panels such as this one composed of individuals from various fields should be able to add significant perspective.

Fourth, to alleviate the emotional and physical burdens of disease, we recommend and support efforts on the prevention of disease through research and epidemiological studies.

Fifth, we urge that attention be given to communication between scientists, physicians, and the public. Not only is this required for better understanding of the expectations of health research, but is is also necessary to aid in the evaluation of controversial modes of therapy such as laetrile and to appreciate the potential dangers of food additives such as saccharine. The public is bombarded by confusing signals regarding health without the benefit of significant educational programs.

Sixth, to provide leadership required for such efforts, the centers for health research and health research training must be maintained. We have experienced a marked erosion of these centers of excellence through spiraling inflation and hospital deficits that have decreased the intramural resources for research. It is recommended that funds be provided to update these obsolete facilities and that the educational cost associated with research training be fully met.

Seventh, it is imperative that the federal government set standards of excellence by example. Regretfully, federal efforts can be inefficient, as exemplified by the low occupancy of public health hospitals. For example, in fiscal year 1976, only 69 percent of the public health hospitals' capacity was used, and only about half of the persons served were primary beneficiaries. Therefore, a prudent evaluation of existing governmental services must be undertaken to decrease inefficiency in this very expensive aspect of the health system.

Eighth, we urge a coordination of federal resources at the managerial level to maximize the flow of knowledge from basic research to the bedside. The impact of regulations on equipment, supplies, and personnel must be balanced with the efficacy of the program. As part of the process of public accountability, we recommend a reorganization of the efforts of our health system so that the pluralistic approach is articulated and not disjointed.

Sister Rosemary Donley, R.N., Ph.D.
President, Sigma Theta Tau
National Honor Society of Nursing

Panel 5 - Unifying Concepts

I am Sister Rosemary Donley, President of Sigma Theta Tau, the National Honor Society of Nursing. I am pleased to be here and to speak to the role and experience of Sigma Theta Tau in funding nursing research. Since its origin in 1922, Sigma Theta Tau has supported the systematic study of nursing.

Our experience is with investigator initiated research. Compared to federal standards a small grant program of $15 to $20,000 a year seems insignificant. Most of these grants have been awarded to doctoral students, many of whom have developed as researchers. Sigma Theta Tau can validate that its money was well spent. We have made available, for the record, a list of research which has been funded by Sigma Theta Tau.

In speaking to unifying concepts, I wish to highlight several levels where integration and coordination would be helpful. These are in the area of financial support, public involvement, the health research continuum and research training. Some federal dollars should be available to extend private, nonprofit and voluntary agency contributions to research by a matching fund mechanism. Citizen involvement in health care delivery and research has been achieved with campaigns against polio, leukemia, birth defects and cancer. It would seem possible to interest and involve the public in research efforts to improve personal health and to increase the ability of health care providers and institutions to deliver care that is directed more by tested findings than habit or intuition.

Many of the areas which affect health, personal habits and life style, for example, seem by definition to lack an organized constituency. Matching federal funds for investigation in health research would mobilize public involvement and participation. This approach would also offer some guarantee of consumer protection. Another area which needs attention and financial support is the translation and communication of research findings into educational and practice settings. A significant variance exists between what is known and what is used in practice. Increasing the support for research without simultaneously exploring methods for transferring the findings will only widen the gap between what is known and what is available to the public. In the area of health research, this effect would be counter productive.

The focus on health research speaks to a continuum of biomedical and behavioral approaches. It also raises exciting questions about care delivery and new directions for research. It supports the development of a new breed of researchers. It seems strange in a time of inflation to speak of extending the horizons of research or developing a new cadre of investigators. It is generally accepted, however, that we cannot continue to finance a system that has not been tested or pay for care that in some instances is unnecessary or inadequate.

Prevention of illness, delivery of health care, the special needs of minorities and the aged, and the plight of the chronically disabled have been subjects of rhetoric not research. These areas need to be addressed.

Professional nurses represent an untapped resource for research into health services. Their focus has been on the care of individuals and groups.

Nurses are committed to the improvement of care and are deeply interested in contributing to the solution of problems in health research.

Nurses are not usually listed on the roster of researchers and frequently are bypassed by traditional networks. Nurses can provide a unifying approach to health research. Their participation should be actively developed.

Remarks Made To The Session:

"Unifying Concepts",

National Conference on Health Research Principles,
Bethesda, Maryland

October 3, 1978

Mr. Chairman, Ladies and Gentlemen, I am Charles Arnold, a physician/epidemiologist, and currently serving as President of the American College of Preventive Medicine. The College is the professional society in the United States for physicians who specialize in preventive medicine. As well, I am Director of the Health Maintenance Institute of the American Health Foundation, a non-profit organization dedicated to research in health promotion and disease prevention.

In his April, 1978, speech to the American Federation of Clinical Research, Secretary Califano clearly formulated the problem for us. I wish to address the integration of research principles which relate preventive medicine to total national health research needs.

In examining the background documents sent us for this conference, my attention was particularly drawn to the unifying research principles developed by a review of the DHEW agencies. I believe they provide an effective frame of reference for our deliberations here. That is, the DHEW agencies combine analysis of the health research problem indicated that to determine the future course of health research one must recognize three broad premises:

1. The social context of health research must be clearly recognized.
2. That a health research continuum exists spanning the cellular to the societal level.
3. Interest in health research within the DHEW agencies is diverse (that is, it is managerially far flung).

Public hearings have been held on these issues as well. It is noteworthy that in the synthesis of the public hearings on health research principles the first premise identified by the synthesizers was the public's desire to be made partners in the establishment of contemporary health research principles.

Increasing attention has been given the possibilities that prevention holds for reducing the burden of illness from the major causes of death in the United States today. Both the public and health professional literature is replete with references to disease prevention and health promotion. It seems reasonable to conclude that preventive health research is a field ready for renewed support at the Federal level. Since it is generally agreed that treatment will not reduce the 65% of deaths resulting from heart, cancer, and stroke disease; more research must be undertaken to demonstrate how prevention can be better applied to them. As a nation, however, we currently lack the research support necessary to test the many underlying concepts inherent in establishing the preventability of these major diseases.

To foster a new Federal emphasis on prevention of these diseases will require us to provide health research support to the basic and clinical sciences of prevention. It is remarkable how the research components of prevention relate to the major premises identified (above) by the DHEW agencies.

"Social Context". Two major research areas in disease prevention are concerned with the social context in which society's health exists: behavioral medicine, and social and economic sciences.

"Research Continuum". In order to further develop prevention, it will be necessary to provide support to the research continuum which are the basic sciences of prevention: epidemiology, biostatistics, and bio-medical research closely linked to epidemiologic studies.

"Diversity in the Field". In order to improve health research concerned with the world around us it will be necessary to provide greater research support to the physical environmental sciences (including occupational health) and the health management sciences.

"Public Partnership". Prevention requires effective communication with the public. More research must be supported directed at health communication between clinical services and their participants. Increasingly we have learned that the publics health behavior is one of the major problems in a variety of chronic illnesses. Only through more effective communication can we improve the partnership necessary to reduce these illnesses.

The support by DHEW of the integration of these research fields can become the pathway by which disease prevention can extend laboratory and small group studies to all society. Which studies have been most encouraging? Briefly, our list includes research into improved techniques of smoking cessation, research into motivation for weight loss and changes in food patterns, research into ways of improving adherence to drup therapy in hypertension.

Money, though urgently needed to advance research and thereby improve the nation's health, will be insufficient unless accompanied by structural changes within DHEW. Two critical structural changes must be made if prevention related research is to reach maturity.

1. The governing councils which determine research policy for all levels of DHEW agencies must include a substantial proportion (perhaps one third) of persons with interest and demonstrated competence in prevention research at the biological and the behavioral levels.

2. To assure more equitable peer review of investigator initiated research that study section composition be carefully analyzed throughout all DHEW agencies to assure that competent prevention oriented persons in a substantial proportion are present on study sections and site review teams.

Were these two conditions to be met within DHEW, there would be far greater support given to prevention related health research that is currently the case without any increase in federal expenditures.

Before closing I must comment upon the potential fragility of policy developments inherent in Secretary Califano's speech before the American Federation of Clinical Research. In those remarks he called for a fundamental research review of health research principles involving both the biological and the behavioral aspects of disease. It is with some regret that I note that nearly 90% of the panel members in this national conference are from the biological sciences or are administrators concerned with biology and/or medical therapy. I am fearful that Secretary Califano's great interest in assuring a broader prospective on health research than currently exists will be subverted, if the report of this conference does not include competently written sections describing the health research needs in the behavioral aspects of disease.

The challenge is clearly before us. I applaude Secretary Califano and the efforts behind the development of this conference. It is my fervent wish that DHEW develop a policy atmosphere so that health research in the federal government can reflect the growing needs of our nation. If that end can be reached, I am confident that the public's interest in prevention will provide impetus for prevention research to receive the support necessary to attain full maturity. As that level of invesigation is retained, there will be great benefit to the nation's health.

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MARJORIE GUTHRIE
Founder/President Emeritus

In 1967, at the time I founded the COMMITTEE TO COMBAT HUNTINGTON'S DISEASE, we stated that our goals were to promote research into the cause, treatment and control of Huntington's Disease, to assist patients and their families, and to educate the families, the public, and the medical and scientific community about what was then called a rare disorder.

Today I see a new challenge. After years of traveling across the country, talking with troubled families, meeting with a variety of health professionals and numerous research scientists, I believe there is need for a model care system which could indeed pave the way for more and better care for more people with similar problems. This too is a research challenge - research in services, research in care.

I started out with Huntington's Disease because my husband, Woody Guthrie, had spent fifteen years in a state institution, and I sat by, believing our situation was, as I was told, hopeless and helpless. Today my perspective has changed. I see that I cannot limit my efforts to the patient with Huntington's Disease, but rather, recognizing the commonality of problems affecting many families with similar neurological or inherited disorders, I am proposing that we can provide, with existing care facilities, a comprehensive program of care. Using a team of health professionals, the family practitioner, the social worker, the specialist, the nurse, all the various health therapists, etc., we could respond to the needs of many patients, regardless of the source of the disorder or the name of the disorder.

Yes, individual differences must be taken into account, but when there are obvious common needs for which help could be provided throughout the course of a chronic illness, we should provide THIS KIND OF UNIFYING CONCEPT that would help patients hold on to a more productive life as long as possible...and when the time comes..let go with dignity.

This team approach has many advantages. We could provide the best care for the least cost. We could avoid unnecessary duplication and help patients and their families gain emotional stability. We could maximize the use of the health professionals and provide a training ground for all members of the health care team. We could encourage compassion, and the facility would serve as a clearing house and information exchange for the professionals and the public. We could improve diagnostic capabilities and help link all the provider agencies.

What seems to stand in the way of accepting this concept is the public and the voluntary health agency's perception that every disease must have its own agency, must compete for American dollars, must build a prestigious image, must maintain their separateness, including their care and research programs. I do not believe that every disease needs a specialized care facility and I want to recommend that there are ways to work together, to share the burdens, to provide that special care for those with similar health problems even while everyone is waiting for the answers to the causes and treatment of their diseases.

I recommend that we must develop vigorous leadership to educate the public and the many voluntary health agencies and the political leadership to appreciate and understand the interrelationships between your disease and my disease.

I would hope that this panel will address this type of unifying concept...in preparation of the final report...and I would be happy to offer more detailed thoughts at the appropriate time.

AMERICAN ASSOCIATION OF COLLEGES OF OSTEOPATHIC MEDICINE

RODNEY T. HOULIHAN, PH.D.

I wish to thank the Secretary, Mr. Califano, for developing this forum making it possible for this presentation, and this panel for their interest in hearing what I have to say.

The basis of my testimony comes from experiences of the last ten years interacting with Federal support of personal fundamental research, university based medical education, and the development of a free standing college of osteopathic medicine for the State Regents for Higher Education in the State of Oklahoma.

During the development of the Oklahoma College of Osteopathic Medicine & Surgery, the interaction with specific agencies of the National Institute of Health has been most gratifying. The State Regents have established a research environment on campus and rural settings for clinical education of all students providing the motivation and self confidence necessary to enter practice in this arena. This establishment has proven to meet its charge to improve health care in the State. However, it can become a microcosm with its own feed back loop not playing a role in identifying the problems and possible solutions of the national population if it is not required to play a role in the national scene. This has been the case with most osteopathic colleges.

As long as significant segments of any system are not a part of the whole, communications cannot take place. The Department of Health Education and Welfare has represented discontinuity throughout its past.

A recent study conducted by the national center for health research participated in by John Barson, Ed.D., President, OkCOMS, has focused on this need for continuity as demonstrated by the following data:

Experiences and needs of patients are not effectively related to professional practice; professional practice is not sufficiently influential in affecting professional education; what is learned in research is generally slow in making it to professional practice, if it ever does.

Discontinuity is evident in and fostered by the differences valued by educators, researchers, practitioners, and the public. Educators and researchers live by a different reward system than practitioners. Improvement in overall health and well-being of the public is not a significant fact for either group. Most academics value science and want to acquire knowledge while practitioners value the art of medical care believing that people could do a lot to improve their own health but will not do so.

One underlying issue to be determined is how students develop attitudes, values, knowledge, and skills which promote health to the population. Continuity must include a feed-back communication means which provides a justifiable basis of the subject areas required in professional health education curricula. Much more substantial effort is required to secure a feed-back loop which represents all cultures involved in and served by the health care system. It is not enough to stipulate a percentage of time spent by medical students in rural or primary care settings. We must establish a mechanism by which the needs of the population at risk can be communicated through the educational process to the research arena and the most effective and scientific solution conveyed to the practitioner for delivery. Patient needs are often perceived by practitioners as nonscientific and outside the professional education process. At the people level methods for assessing the developed performance are also needed in order to complete the feed-back loop. The importance of decision making with regard to financing health professions education and reimbursement for practice ranks high among issues needed to be addressed by research. The impact of any public policy on educational systems, applied research, and health care delivery cannot be viewed in isolation.

Studies which are more holistic in their approach to the system of health services are likely to yield a greater harvest than those which are reductionistic. Studies will be more useful if they exploit the dynamic and changing character of the health needs of the population anticipating a changing system with changing relationships between the sectors. Studies which transcend the concerns of particular professions are more likely to yield information useful in developing effective-public policy.

In conclusion, I would like to recommend some type of an over site committee or process representing all facets of a feed-back system be established to insure participation and communications among people, education, researchers, and staff of the HEW.

Association for Academic Health Centers

Office of the President

Ronald P. Kaufman, M.D.
Vice President for Medical Affairs,
The George Washington University
On behalf of the Association of
Academic Health Centers
Presentation to Panel 5
(Unifying Concepts)

September 1, 1978

The Honorable Joseph A. Califano, Jr.
Secretary of Health, Education & Welfare
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D. C. 20201

Dear Mr. Secretary:

On behalf of the Board of Directors of the Association for Academic Health Centers, I am pleased to respond to your invitation to submit our views on the principles which should guide the allocation of Federal monies in support of the nation's health research.

While the important issue of health research is deserving of a lengthy treatise, our response will be limited to a presentation of selected principles for your consideration. Some of our comments will, indeed, merely serve to reinforce a number of the important points contained in your excellent presentation of April 29, 1978.

1. While we support the view that the nation's health research must be responsive to issues and illnesses which are currently compromising, the health and well-being of the citizenry, we strongly endorse your statement that a long-term investment must be committed to basic research. While you stated that "there must be freedom to pursue research topics that are not immediately relevant," we respectfully submit that mere freedom for such pursuit does not adequately address the issue. Indeed, future strategy must assure that both basic and more immediately relevant research be pursued. Such assurance will require a conscious decision to allocate a portion of total Federal dollars to basic research, thereby protecting those funds from the inevitable social and political pressures of the day.

2. We applaud your principle that attention must be directed to the development of future investigators. In the absence of a strategy of the type you are now requesting, training programs suffered early and disproportionate cut-backs during the past decade of fiscal constraints. We in academic health centers have observed this phenomenon with increasing concern and have been led to the view that training money will be a continuing victim of open competition for limited dollars. Accordingly, we urge that five-year funding strategy reflect a commitment to support of training and development of young investigators.

3. We wish to convey our strong support for preservation of the project grants mechanism for distributing research dollars. While there is a place for the contract grant mechanism, the trend to depend too heavily

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on this approach must be checked. The future will be best served by capitalizing upon the imagination and innovative strengths of the nation's biomedical research community.

4. In contemplating the future of the nation's health research efforts, we wish to state our unqualified view that the existing peer review mechanism should be maintained as an essential element in any system of Federal support.

5. The pool of the nation's research manpower now includes representatives of disciplines not traditionally identified with biomedical research. The research challenges of the future, however, will require contributions of those from a wide spectrum of professional disciplines. A strategy for the future allocation of Federal monies must include mechanisms which accommodate to the changing nature of the research community.

6. The development of the nation's current biomedical research capacity could not have been achieved without the commitment of large sums of money for the construction of physical facilities. As you so wisely described, the quality of physical plants and equipment has undergone serious deterioration. It is essential that plans for the future include appropriate programs for construction and renovation of research facilities.

7. As a principle to guide future strategy we wish to emphasize that the nation's health research efforts must not be compromised by the stifling effect of increasing Federal regulations. Bureaucratic excesses must not be permitted to divert money and time away from our health research efforts.

8. While we strongly support planning for the future, we caution against the development of plans which are so firmly established as to inhibit the ability for response to opportunities presently unforeseen. Flexibility to exploit a scientific "breakthrough" or pursue serendipitous discoveries must be preserved. It is recommended that a financial reserve for such purpose be included in a strategy for the future.

Thank you for your solicitation and consideration of the above comments. We applaud your efforts on behalf of the nation's health research endeavors. The Association for Academic Health Centers will be pleased to provide further assistance as you proceed with your important task.

Sincerely yours,

M. K. DuVal

Merlin K. DuVal, M.D.

MKD/jmd

Remarks of Carl Stenzler, President

Pennsylvania Diabetes Institute

At the National Conference on Health Research Principles

Before Panel 5, Unifying Concepts

(Presented by Dr. Christian Klimt)

Mr. Secretary and distinguished members of the Panel:

Your message is refreshing. This administration, through the good office of the Secretary, is initiating a comprehensive review of Federal support for basic biomedical research. The dilemma posed by enormous needs and limited resources obviously will be resolved in the public interest by your leadership.

The Pennsylvania Diabetes Institute offers the following recommendations:

1. Research should be funded in proportion to impact on Government.

   The dilemma of annual competition for the same limited dollars can be reduced or dissolved with the application of measurable criteria specific to impact on Federal Government. Among them are:

   1. Number of people affected

   2. Loss to GNP

   3. Reduced Federal tax returns

   4. Cost of Federally-funded health care and health delivery and pending National Health Insurance

   Such a disease index more fully developed in the manner of Standard and Poor or Dunn and Bradstreet will provide measurable dimensions to new disease--identifying the degree and extent of impact on our Government.

2. The Pennsylvania Diabetes Institute recommends basic criteria, similar to information revealed in Standard and Poor, Dunn and Bradstreet, to be fully developed and made available to the general public, the Executive and Legislative branches of our Government as a basis for judicious policy decisions: (i.e.) Step one through four described in first recommendation.

Supplementary base-line information could include:

A. Definition or description of the disease

B. History of the disease

C. Proliferation potential

D. What do we know about the disease?

E. What do we think we know about the disease?

F. What we do not know about the disease

G. Priority problems of the disease

H. History of research accomplishment as measured by improved quality of patients' living standard

I. Are the new therapies long term? Short term? Encumbered by side effects?

J. What are the bottom line dividends for dollars invested in 1950 to 1978?

Universal diseases such as diabetes that invade more than one National Institute should be tendered special treatment in the Office of the Director, NIH. The present mechanism which creates a lead Institute tilts significant research funds toward that Institute and crumbs to all others.

3. The Pennsylvania Diabetes Institute recommends legislative or executive mandates be estabished that would endow the Office of the Director of NIH all powers not specifically delegated to the individual directors of each National Institute. This collated authority will allow the Director of NIH to harness one, several, or all National Institutes to co-planned, co-trained, co-funded research.

By coordinating all the National Institutes, objectives for expanded research are increased geometrically--at the same time the per Institute costs for research contribution are reduced.

Mr. Secretary: During the past year, PDI has been researching major chronic diseases affecting the American people. Hard figures or numbers affected are not available. Data retrieved from NIH, NHEC, JDF, ADA, KF, AHA, etc., are incomplete, inadequate, deceptive, dated, incompatible and inaccurate.

In addition, information is almost always slanted toward the interest groups seeking Federal investment of taxpaper dollars in their work. As a result, statistics tend to represent more fiction than fact.

Mr. Secretary: In closing, PDI urges 1) the Department of HEW, as represented by its components to complete, update and improve current medical information and statistics; 2) to substitute orderly accounting and business principles as guidelines for funding biomedical research--in place of annual chaos framed in staged lobbying, emotion and political manipulation; 3) the Department of HEW to define freedom of scientific communication as not giving a scientist license to present his limited hypothesis to the public as a "cure;" 4) that future funding be based on "Impact on Government."

Thank you very much, Mr. Secretary.

I am Mrs. Eleanor Kohn of Danbury, Connecticut. I am testifying today as Chair of the National Research Committee of the Mental Health Association, an organization of some million volunteers which addresses itself, through social action, to the needs of the mentally ill, toward the prevention of mental illness and the promotion of mental health.

In this capacity, I shall try to focus my remarks on those areas of research planning where we, as consumer advocates in the mental health field, feel we can add still another perspective to the salient comments which you are hearing today, many of which come from the point of view of the professional community. We do not speak for a specific discipline nor a particular approach. Because we function at a local, state and national level, we are in a position to bring to you concerns from the public at large.

An overarching problem which the research community needs to face is the fact that health research has never been seen as an important priority by our society. Demands for service abound -- as they should. Cutbacks in service produce loud protests -- as they should -- but cutbacks in research funding cause scarcely a ripple. While our Congress considers spending two billion dollars on a single aircraft carrier, the entire bio-medical research effort cost our Federal government only three billion dollars in 1977. Health research constituencies find themselves in the position of competing with each other for nickles and dimes when we might better be turning our energies to finding ways of educating and convincing the public that the meager two percent of the total national health expenditure invested in health research reflects a shortsighted and ill-considered policy. To change that policy, supporters of health research will have to expand their skills to deal with issues arising in legislatures as well as in laboratories.

Having said that, I turn my attention to other funding issues of special concern to mental health proponents.

First we call your attention to the continuing gross inequity reflected in the commitment, or lack thereof, of our national resources to mental illness research. Mental illness drains over eight billion dollars from public coffers to care for the mentally ill, yet less than 1.5% of that staggering total is being invested in research on causes and cures. Any future planning effort must give needed attention to this glaring imbalance.

Another facet of the same funding problem is equally disturbing to us. Not only is there little coherent relationship between the cost to the public of mental illness and dollars invested in research but there is even less reality when one looks at the prevalence and incidence of mental illness in comparison with other illnesses. 33% of all hospital beds in the country are occupied by the mentally ill. Each year 35,000 Americans take their own lives as a result of severe depression. The President's Commission on Mental Health reported that one in seven Americans needs some form of mental health care. It is the nation's #1 public health problem and yet only 3.5% of the Federal health research dollar goes into mental health research. A discrepancy of that magnitude demands remedial action.

Our primary recommendation therefore, calls for a national health research policy which includes consideration of these three funding issues:

1. The need to develop strong public awareness and demand for all health research so that it can take its logical place as a national funding priority;
2. The establishment of a mental health research policy which calls for the investment of 5% of the public cost of treating mental illness as a reasonable long range goal;
3. The adoption of a national health research policy which reflects in its allocation of resources both the numbers of people affected by the illness and its social cost.

A second recommendation concerns the increasing importance of public participation in research activities. The availability of research funding has become more and more entwined in the political process. It is that process which determines to a great extent how far and how fast the research enterprise can move. In the final analysis, the public will decide where its tax dollars should be spent. It therefore becomes prudent and imperative that the research community encourage the development of a knowledgeable and informed public which can participate in the debate which shapes research policy and support.

In addition, increasing demands for public accountability make it all the more urgent that the flow of information be a two way street. Providing adequate input on which the public can base informed judgment will in the long run broaden and strengthen support for scientific inquiry.

Adding to the growing public perception of its right to participate in debate on the spending of tax dollars, is the growing public concern about who is spending those research dollars, on what and under which controls. The public is insisting on being heard and that insistence will surface in extreme Proposition Thirteen-like reactions unless and until the research community finds ways of using that public concern in a positive and supportive fashion.

To this end, the Mental Health Association recommends support for the concept of increased public representation on all research decision making bodies.

A third recommendation from the Mental Health Association deals with the dearth of adequate research in the health services area. If we are to bring about any improvement in the capacity of publicly supported agencies, which are now providing the bulk of the services, to improve the lives of the chronically ill and to prevent the development of chronicity in others, more data on effective strategies must be produced. At a time when hospital cost containment has become a household word, there must be research devoted to it. In the mental health field particularly, this will call for a fresh look at how and where and by whom that kind of research can most logically be carried out. It may require a mix of Federal and state research efforts or perhaps a coalition of public and academic efforts. It will most certainly require that quality research activity be encouraged, not just in research labs, academic centers and teaching hospitals, but also in those agencies and institutions where public dollars are now being spent to provide services which all too frequently are custodial at best.

Our final recommendation, therefore, calls for a research policy which affirms strong support for basic research but along with that, urges increased attention to the need for stimulation and support of health services research at a much broader level than is now the case.

These recommendations reflect the policy decisions of the Mental Health Association and we pledge our cooperation in working with the research community to implement them. Thank you.

10/3/78

STATEMENT ON UNIFYING CONCEPTS

Ismet Karacan, M.D., D.Sc.

Past Chief Officer, Association for the Psychophysiological Study of Sleep
Member, Executive Committee, Association of Sleep Disorders Centers
Director, Sleep Disorders Center, Baylor College of Medicine, Houston, TX
Associate Chief Of Staff for Research and Development, Houston V.A. Hospital
Professor of Psychiatry, Baylor College of Medicine, Houston, TX

I and my colleagues from the Association for the Psychophysiological Study of Sleep and the Association of Sleep Disorders Centers thank you for this opportunity to express our views on health research principles. My comments will be directed mainly at what I think is a critical aspect of the scientific endeavor, namely education. In reading the material that was provided before this conference, I was surprised to note that education was rarely directly mentioned. In my view, education, in its widest meaning, can contribute significantly to the speedy incorporation of new knowledge into clinical practice. It can also serve the legitimate need of increasing communication with and accountability to the public.

I will describe two of my own experiences to illustrate some of the problems that education must overcome. One of my primary research interests for the last 15 years has been the phenomenon of nocturnal penile tumescence. Healthy men experience three or four penile erections during a normal night of sleep. At first, research on this topic was pursued primarily because of its implications for understanding of the psychophysiology of sleep. More recently, breakthroughs have led to use of sleep erections in the differential diagnosis of organogenic and psychogenic impotence. This is a clear example of the movement of a fundamental research finding to application in the clinical setting. But, in spite of the best efforts of my colleagues and I to bring this new technique to the attention of practitioners and patients, we have managed to inform only a very small number of persons who might use or benefit from it. Further, for patients who do reach us for evaluation, there is no assurance that third-party payers will consent to reimburse any portion of the costs of the evaluation, even though an accurate differential diagnosis will prevent needless expenditures on inappropriate or ineffective alternative treatments.

My second experience was a rather distressing inquiry by my local medical society into the propriety of my advertising for healthy research volunteers. The instigators of the inquiry believed the advertisement was a breach of the medical code regarding solicitation of patients. I doubt if I could have resolved the issue satisfactorily if I had happened to be advertising for volunteers for research on insomnia.

Science is by definition a social process, for it involves not only the discovery of new knowledge, but also the communication of that knowledge. The trouble has been that we have defined the society too narrowly. Many of us have been content to publish our findings in journals that colleagues in our own fields will read and then to return to the laboratory to pursue our work. Perhaps we make a few talks at local Continuing Medical Education courses or at national meetings, but these talks are not considered to be integral to our research program.

I propose that agencies which support health research actively provide incentive for researchers to engage in professional and public education in a more systematic way. This objective might be easily achieved if the agency stated explicitly that it encouraged investigators to disseminate research findings that resulted from any study it supported.

This blessing of widespread dissemination of new research knowledge would be beneficial in several ways. First, the description of a new research finding undoubtedly has much greater impact on public consciousness when it comes from the discoverer than from a federal employee, however well meaning, or from a federal publication. As researchers come out of their laboratories more regularly and interact directly with the public, I am convinced that the public will develop greater respect for the work the researchers do. But the interaction will not be only one way. I also believe the researchers will gain insight into the health problems that concern people, and this insight will serve to guide research into areas that the public is willing to support. As the public becomes more knowledgeable about research, so will special segments of the public, such as community practitioners, scientists in different but potentially related fields, and decision-makers for health insurance plans. As these people become more knowledgeable, they can contribute to the application of the research in the clinical setting, its expansion into related areas, and its incorporation into health insurance plans.

In brief, I believe there must be explicit and active involvement of researchers in the education of every segment of the public that may benefit from new research findings. There need be no information middleman. Rather, the researcher should be encouraged to assume his or her share of the responsibility for speeding the movement of fundamental research to the clinical setting and to public awareness and acceptance.

In the time remaining, I want to briefly mention several other points. I and my colleagues are particularly aware of the problems that researchers in new fields face in obtaining research support. I believe we must develop some method of assuring that promising new areas are quickly identified by funding agencies, and that research proposals from these areas are adequately and fairly reviewed. Society suffers most in the long run when new discoveries are ignored. Perhaps there needs to be an ombudsman for researchers in new fields.

Another point is that we must find some method of increasing incentive to do applied research. In my opinion, the V.A. system of supporting co-operative studies is a promising model. Of critical importance is that the initiative for the research comes from individual researchers or from groups of researchers. This aspect contributes to interest in the program by researchers who might otherwise avoid applied research. More researchers might be willing to undertake applied research if funds were available for co-operative studies.

Finally, it seems to me that we American health scientists must receive more encouragement to seek simple and creative solutions to research problems. Our sophisticated technological society tends to create the view that real solutions must by definition be complex and costly. Perhaps if we were freer financially to study the scientific process in countries with more limited resources we could develop more cost-effective methods of attacking our research problems.

Name: Theodore Cooper, M.D.
Affiliation: Association of American Medical Colleges
Panel: UNIFYING CONCEPTS

I am Theodore Cooper, M.D., Dean of Cornell University Medical School. I am pleased to appear before this Panel to present the views of the Association of American Medical Colleges on maintaining and strengthening the biomedical and behavioral research capability of this nation. The Association has provided to the Department extensive, carefully considered remarks on the unifying concepts which support all biomedical and behavioral research but with special emphasis on the research programs of the National Institutes of Health. The AAMC position was developed with input from than 40 professional and academic societies. Because of the severe limitation of time available in which to present our views to this Panel I must confine myself only the the recommendations of our Association; however, I have sufficient copies of sections of our Biomedical and Behavioral Research Policy statement which bear on the problem before you so that you may each have a copy at this time to aid your deliberations.

Developing Public Involvement in Health Research Policy - The public has come to have high expectations for improvements in health as a result of its unflagging support of biomedical and behavioral research over the past 30 years. In part, these high expectations have resulted in an understandable desire for more accountability in the biomedical research field but it is often difficult to provide proof of a reasonable return on the research effort.

There continues to be a need to provide information to the public about the nature of scientific research, the accomplishments that can be reasonably expected and the limitations of science. The AAMC and its constituents recognize the need to participate in public education campaigns to a much greater degree than in the past. This would stimulate greater public discussion of the allocation of funds to various fields of research, emphasize appropriate goals for research, and ensure a better understanding of the costs and benefits of expected gains.

Therefore, the Association recommends that:

- The biomedical and behavioral research community encourage efforts to increase public understanding and support of biomedical and behavioral research policy. The advisory council apparatus of the NIH and ADAMHA should be strengthened to assist in this objective. Scientists must assume a responsibility to assist the public in setting realistic goals and timetables for research efforts.

To strengthen the mechanisms of reviewing and coordinating research, the AAMC recommends:

- The Public Health Service Act should be modified to permit confidential, closed panel peer review of grant and contract applications so as to obtain high quality reviews of proposals, to prevent invasion of privacy of the applicants, to safeguard clinical trials, and to protect proprietary interests.

- The scientific community through its representatives in the peer review system must assume responsibility for critical evaluation of all research projects particularly those included in multiproject grants or contracts, so that lower quality research is not funded and funds are allocated to the most promising avenues of research.

To improve the structure and function of the institutions which support research, changes in the management of the Federal research endeavor are recommended:

- Efforts should be made to strengthen the effectiveness of the Director, NIH by creating a special director's fund.

- The programs of the National Cancer Institute should be placed under the authority of the Director of the National Institutes of Health. The research programs of ADAMHA should be carefully monitored with a view to placing them in NIH should they fail to prosper in ADAMHA.

- The NIH and ADAMHA advisory councils should have a greater role in establishing a balance among research activities.
- The advisory councils should be protected from political intervention.
- The Director, NIH, assisted by his advisory committee should establish criteria for the initiation and evaluation of centers and other broad programs.

To protect their health and improve management of their illnesses, the American people should continue their commitment to biomedical and behavioral research and support it from diverse sources. Stable funding should be assured and adjusted annually to reflect research needs and costs and to permit exploitation of new research and development opportunities. The Federal government's primary but not exclusive role in this area should be reaffirmed

The Association further recommends:

- AAMC strongly endorses the investigator-initiated project grant as the most appropriate mechanism of support of basic and applied research. Consequently, investigator-initiated projects should have priority over centrally directed funding mechanisms which are more appropriate for clinical trials, research/demonstration centers and other targeted activities. Any erosion of support for investigator-initiated activities, regardless of cause, should be immediately remedied.
- A vigorous program of high quality research applied to clinical problems should be supported by Federal grants, private philanthropy and by industry.
- The transfer of research-proven technology to health care should be the mission of a number of Federal agencies, private organizations and industry. A fund for the support of technology transfer activities should be created and related to the health care budget. It should be administered by an agency responsible to the Assistant Secretary of Health assisted by an advisory council.

Theodore Cooper, M.D.
Association of American Medical Colleges
Excerpts from: AAMC Biomedical and Behavioral Research Policy Statement

GOAL 3: DEVELOP EFFECTIVE PUBLIC INVOLVEMENT IN THE FORMULATION OF RESEARCH POLICY.

The public has come to have high expectations for improvements in health as a result of its unflagging support of biomedical and behavioral research over the past 30 years. In part these high expectations have resulted in an understandable desire for more accountability in the biomedical research field but it is often difficult to provide proof of a reasonable return on the research effort.

There continues to be a need to provide information to the public about the nature of scientific research, the accomplishments that can be reasonably expected and the limitations of science. The AAMC and its constituents recognize the need to participate in public education campaigns to a much greater degree than in the past. This would stimulate greater public discussion of the allocation of funds to various fields of research, emphasize appropriate goals for research, and ensure a better understanding of the costs and benefits of expected gains.

Public participation is not appropriate in the highly technical review of specific applications by initial review groups (study sections) or in decision making about specific research projects. However, the appointment of public members to the advisory councils of the separate Institutes, to program development panels, and to the NIH Director's Advisory Council is a desirable way to involve the public in the formulation of research policy. To make public participation more effective, public members should be selected for their interest and abilities rather than for their political affiliation. Properly constituted advisory councils are an excellent public forum for the discussion of research strategy and other public policy matters. The advisory councils should have more effective representation of the public and be more active in assessing areas needing more or less research emphasis or areas in which demonstration programs are likely to be effective. Means should be sought to assure the education of the public about the advances of biomedical research and the reasonably expected benefits of such research as well as potential, real, or imagined hazards that can arise from research. In these ways public opinion can be informed and mobilized on the important questions of research policy and strategy, such as the balance between basic and applied research and the evaluation of the continuum by which new knowledge is applied to solving practical health problems.

Recommendation 3

- The biomedical and behavioral research community should encourage efforts to increase public understanding and support of biomedical and behavioral research policy. The advisory council apparatus of the NIH and ADAMHA should be strengthened to assist in this objective. Scientists must assume a responsibility to assist the public in setting realistic goals and time tables for research efforts.

Theodore Cooper, M.D.
Association of American Medical Colleges
Excerpts from: AAMC Biomedical and Behavioral Research Policy Statement

GOAL 4: STRENGTHEN THE MECHANISMS OF REVIEWING AND COORDINATING RESEARCH.

The continued assurance of the quality of biomedical research depends to a large degree on the NIH peer review process. While the peer review concept as developed at the NIH has had unparalleled success in assuring the allocation of funds to the best possible research, a number of concerns have been voiced about the scientific peer review system in general. The NIH system has been scrutinized extensively by the President's Biomedical Research Panel, by the Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, and by a committee appointed by the NIH Director. The NIH committee has recommended changes that would improve the system. Each of these groups recommends statutory exemptions to permit the continued closure of peer review sessions. Such closure protects the confidentiality of the peer evaluation and assures frank, uninhibited, and therefore, the most searching, critique of research protocols. The AAMC agrees that the Public Health Service Act should be modified to permit closure of study section and council meetings during review of individual research applications and when qualifications of individual scientists are discussed. Patent and proprietary rights of investigators would be protected by such modification and premature disclosure of clinical trials and similar data prevented. The AAMC has repeatedly urged such an amendment to the Public Health Service Act to modify the deleterious effects of the Freedom of Information and the Federal Advisory Committee Act on the peer review process and the conduct of clinical trials. Meetings would be open to the public in all other circumstances. In turn, biomedical and behavioral scientists must be alert to their responsibilities in several areas including provision of

- The scientific community through its representatives in the peer review system must assume responsibility for critical evaluation of all research projects particulary those included in multiproject grants or contracts, so that lower quality research is not funded and funds are allocated to the most promising avenues of research.

- The cause and effect of work load increases and other deleterious influences on the peer-review system should be carefully monitored and appropriate corrective action taken.

Theodore Cooper, M.D.
Association of American Medical Colleges
Excerpts from: AAMC Biomedical and Behavioral Research Policy Statement

GOAL 5: IMPROVE THE STRUCTURE AND FUNCTION OF THE INSTITUTIONS WHICH PERFORM RESEARCH AND THOSE WHICH SUPPORT RESEARCH SO AS TO PROMOTE THE ORDERLY TRANSFER OF RESEARCH FINDINGS TO PATIENT CARE.

Changes in the Management of the Federal Research Endeavor: The Federal share of the support of biomedical and behavioral research is a major and irreplaceable part of the total effort. However, certain changes are needed to improve the administration of the Federal share of that effort.

The AAMC has repeatedly stressed the desirability of strengthening the authority of the NIH Director. Among the recommendations have been the lessening of political influences in the appointment and term of the Director. Although these remain important considerations, there are other changes in the authority of the NIH Director which are now more urgent. The AAMC believes that the Director should have available a small fund to allocate to promising programs at his discretion but with the assistance of an appropriate advisory apparatus. It is also advisable to re-establish the authority of the Director over the programs of the National Cancer Institute. The separation of the National Cancer Institute from the remainder of NIH and the creation of the President's Cancer Panel in response to special interests has assured that the cancer effort is now well established. It is now possible to return this research authority to the NIH Director and to assure this sound concept of science management for the future. The combination of this move with the strengthening of the NIH advisory council structure would achieve a significant improvement in programmatic and scientific coordination.

Although the research programs of ADAMHA, particularly of the National Institute of Mental Health, have been in large part neglected as the agency turned its attention to mental health service programs, the AAMC believes that with new leadership an opportunity now exists to effect substantial contributions in behavioral research. For this reason the AAMC does not recommend that NIMH be placed under the auspices of the NIH at this time. A continuing review will be conducted and the AAMC may, in the future, favor such unification if ADAMHA's research functions continue to be obscured by service commitments.

The role of the advisory councils in the work of NIH and ADAMHA should be strengthened. The councils are uniquely able to assess regularly and thoroughly the overall status of research programs within the various Institutes and the NIH and ADAMHA. A primary function of the advisory councils of NIH and ADAMHA should be the assessment of areas which need additional research emphasis and the identification of those areas which justify increased financial support. These same councils should provide input and advice on research funding and should identify those areas which lag in the application of basic research findings to clinical practice. Such an assessment would make overall research strategy development more apparent and unified. The advisory councils should be appointed without undue delays and should be protected from political intervention in the selection of council members. The advice of Institute directors should be given greater weight in the appointment of professional members.

Problems continue to surround the initiation and management of multidisciplinary and research/demonstration centers and large program project grants. As a matter of public policy the broad criteria for the employment and evaluation of such programs should be set out by the Director, NIH, with advice from his advisory committee. This policy can then serve as a guide to the various Institutes and prevent fragmentation, unnecessary competition, conflicting guidelines, and overlapping functions. In a similar way policies for starting new programs or terminating others should be developed by the Director.

Recommendations 5

- Efforts should be made to strengthen the effectiveness of the Director, NIH by creating a special director's fund.
- The programs of the National Cancer Institute should be placed under the authority of the Director of the National Institutes of Health. The research programs of ADAMHA should be carefully monitored with a view to placing them in NIH should they fail to prosper in ADAMHA.
- The NIH and ADAMHA advisory councils should have a greater role in establishing a balance among research activities.
- The advisory councils should be protected from political intervention.
- The Director, NIH, assisted by his advisory committee should establish criteria for the initiation and evaluation of centers and other broad programs.

Relationship Between the Federal Government and Academic Institutions: The AAMC is concerned about both the propriety and cost of unchecked Federal intrusion into the academic research environment. Federal regulation may become "over-regulation," especially as compliance requirements are imposed by both the Federal legislative and executive branches and by state and local governments, often acting independently and without awareness of the cumulative cost such regulations have on multi-purpose academic institutions. Each agency may impose a few regulations which when aggregated become intolerable in terms of cost of compliance, administrative delays and paper work, and which may even conflict in purpose. For example, Occupational Safety and Health Administration regulations affect research laboratories in many ways mandating expensive and often ludicrous changes on those laboratories. The Departments of Transportation, Interior and HEW all have regulations relating to experimental animals. Even affirmative action has had an impact on research costs. Clearly, Federal oversight is needed, but better coordination is necessary.

The Government should also be aware of the unbalancing effect of certain Federal programs on the academic institutions which carry them out, since the performer institutions usually have a number of goals that are not all congruent with the Federal goals. For instance, Federal regulations may seriously distort the academic environment by making it necessary for the institution to alter some of its programs in order to comply with all the requirements of Federal sponsored programs.

Recommendation 5

- The AAMC recommends that more careful attention be given to the costs and unintended effects that administrative requirements and regulations have on the ability of institutions to perform their research mission. The Federal government should strive toward a goal of minimizing the burdens imposed by regulations.

Theodore Cooper, M.D.
Association of American Medical Colleges
Excerpts from: AAMC Biomedical and Behavioral Research Policy Statement

GOAL 6: ASSURE ADEQUATE SUPPORT FOR ALL ASPECTS OF THE RESEARCH PROCESS.

In the past 10 years total national expenditures from all sources for biomedical research and development have increased two and one-half times. In 1975 the total amount invested in these activities was 4.6 billion dollars. However, during the same decade total national expenditures for health tripled. As a result biomedical research expenditures declined as a percentage of total health expenditures from a high of 5% in 1966 to 3.8% in 1975. This is a low rate of investment for a research dependent industry in which new knowledge must be viewed as the best long term strategy to understand, cure, ameliorate and prevent disease. While it is true that research has led to better understanding of the outcome of disease, this has often led to expensive "half-way technologies" which deal with the results of disease processes. Although only partially satisfactory, those technologies often represent the best or only treatment available to the practitioner. Far better for the control of cost of disease-- and far more difficult to achieve--is research which leads to the prevention of disease before it occurs.

It has been suggested that support for biomedical and behavioral research be fixed as a percentage of national health expenditures and a frequently cited figure has been five percent. However, the escalation of national health expenditures due to increases in health care services provided through third party payments, rising labor costs, and greater use of expensive diagnostic procedures and "half-way technologies" makes a fixed percentage rate hard to justify.

Therefore, it is more reasonable to relate future funding for biomedical research to current levels of support with annual adjustments for inflation, for the increased cost of sophisticated investigative tools and for investment in new and promising areas of research as they emerge.

The best method of support of applied research is through traditional individual and program project grants, whether from the Federal government, from private foundations or from industry.

Activities to test the safety and effectiveness of new biomedical knowledge, to demonstrate new technology to health care personnel and to educate the public about the significance of new research discoveries are very difficult to control or perform well. The need for determination of cost effectiveness, education and demonstration projects, and dissemination of new technology is unquestionable. The AAMC suggests that responsibility for these activities should be shared by public agencies, by private philanthropy and by industry. The public sector cost of these activities could be borne by a revolving fund established in DHEW equal to a small percentage of the total Federal health care budget. This fund should be clearly separated from the budgets for biomedical and behavioral research. An agency responsible to the Assistant Secretary for Health, DHEW, and assisted by an advisory council which includes public members should make appropriate allocations of these funds to the proper agencies, to academic institutions or to industry.

Cooper
AAMC

Recommendation 6

- To protect their health and improve management of their illnesses the American people should continue their commitment to biomedical and behavioral research supported from diverse sources. Stable funding should be assured and adjusted annually to reflect research needs and costs and to permit exploitation of new research and development opportunities. The Federal government's primary but not exclusive role in this area is affirmed.

- AAMC strongly endorses the investigator-initiated project grant as the most appropriate mechanism of support of basic and applied research. Consequently, investigator-initiated projects should have priority over centrally directed funding mechanisms which are more appropriate for clinical trials, research/demonstration centers and other targeted activities. Any erosion of support for investigator-initiated activities, regardless of cause should be immediately remedied.

- A vigorous program of high quality research applied to clinical problems should be supported by Federal grants, private philanthropy and by industry.

- The transfer of research-proven technology to health care should be the mission of a number of Federal agencies, private organizations and industry. A fund for the support of technology transfer activities should be created and related to the health care budget. It should be administered by an agency responsible to the Assistant Secretary of Health assisted by an advisory council.

American
Diabetes
Association, Inc

600 5th Avenue New York, N. Y. 10020 Telephone (212) 541-4310

STATEMENT OF THE AMERICAN DIABETES ASSOCIATION

BEFORE THE CONFERENCE ON HEALTH RESEARCH PRINCIPLES

October 3-4, 1978

The American Diabetes Association, the nation's largest voluntary health agency concerned with the problems of diabetes, appreciates the opportunity to present its views on health research principles. Our organization represents more than 3,000 leading health professionals working in the area of diabetes, as well as hundreds of thousands of patients and their families around the country. We are vitally interested in the subject of health research principles as both a governmental and private sector issue. Our own funding of research continues to grow each year, and in calendar year 1977 totalled almost $1,700,000. Although we are confident that our research expenditures will continue to grow each year, we accept the reality that fiscally we can only be a "junior partner" to the efforts that must be undertaken by the government. This was shown clearly in the 1975 report of the National Commission on Diabetes, where it was estimated that 94% of the diabetes research effort was funded through the Federal government, with 6% allocated through all voluntary health agencies.

I would like to address my comments today to the subject of "unifying concepts." The American Diabetes Association believes the Federal government has to continue to play the major role in the support of both fundamental and clinical research. The disease entity, or organ, is irrelevant because the benefits of such research are universal. We have never suggested nor would we support any efforts to decrease the level of funding for fundamental research in our area or any other. We hold the proposition that the amount of funds currently being spent for fundamental research in a wide variety of areas, including diabetes, is insufficient. Incrased funding of fundamental research in diabetes will result in an increased understanding of fundamental life processes which will apply to a wide variety of diseases.

It is simply too narrow a view that basic research in the area of diabetes or any other single disease will only benefit the health of those individuals with those diseases. Fundamental research in the area of immunology has found a great and useful application in the area of cancer; fundamental research in the area of hypertension and angiotensin converting system has yielded a new and important diagnostic test for the diagnosis of an important lung disease, sarcoidosis. Fundamental research in the area of metabolism in an attempt to understand the process of cancer has led to a greater understanding of the metabolic abnormalities which occur in diabetes. Such examples of the value of fundamental research abound.

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*Member of the Board of Directors by Reason of Office Member of the National Health Council

We do not consider diabetes to be a "disease of the month" since diabetes is a disease with a profound impact on all organ systems, and our concern encompasses a great variety of Federal agencies. Diabetes benefits as much from research carried out by the National Institute of Allergy and Infectious Diseases as it does from NIAMDD or the Eye Institute. We have therefore endorsed the report of the National Commission on Diabetes, and the subsequent report of the National Diabetes Advisory Board. We support both groups' recommendations for increased funding of basic and clinical diabetes research, and we will advocate such increases to both the Administration and Congress.

We urge that investigations at both the basic and clinical level be increased for common chronic diseases because health care costs are going to continue to burgeon unless some causes for these diseases are found. In the same vein, some investigational resources should be allocated to minimizing the present cost spiral. We agree with the principle enunciated by Secretary Califano that "HEW-supported research must be more effectively oriented...." if that means finding out the best way to deliver care or set standards. There are excellent examples in the diabetes community of how patient education can directly control such costs as the frequency of hospital admissions and at the same time provide more effective health care.

We also concur that "government-supported research must have a strong orientation toward improving the quality of our nation's health...." if that means supporting recommendations from the National Diabetes Advisory Board such as the need for additional funding to encompass behavioral research in diabetes -- an area that would have basic implications in mental health aspects of all chronic diseases. Or increasing the attention paid to research into nutrition, basic studies which can't be separated from basic studies on diabetes.

We would also like to emphasize that, regardless of the amount allocated to research studies, a substantial sum must be appropriated to support investigators to be sure that the supply never dwindles. For a rapidly growing research program, NIH experience has demonstrated that needs are best fulfilled when training budgets approximate 16% of research budgets. The current ratio in most Institutes is much less than that and should be increased.

In summary, we believe strongly in support of fundamental research and do not believe that the efforts of the Diabetes Association have been detrimental to that effort. We strongly support the peer review process and feel that it is the best mechanism to take advantage of new opportunities in fundamental research. We support the expansion of the concept of fundamental research into the areas of behavioral medicine and epidemiology but suggest that these efforts be funded by additional monies and not be a diversion of basic research funds of current projects. We are concerned that Secretary Califano's speech might be interpreted to suggest that the amount of money that the country is spending for research is fixed, that it should not be increased, and that all planning should take place within the constraints of the current research budget. We take a strong position that the increased research efforts in a wide variety of areas mentioned by Secretary Califano should be funded by additional efforts in research. The total health budget in the United States exceeds $160 billion; the total biomedical research effort in the United States is less than $3 billion. Most industries spend 5-10% of their funds in research. We believe that this is a realistic percentage of funds to be spent in the health area and suggest that $4 to $8 billion a year in research in the health/biomedical area is not unreasonable. Even if increases to these levels are not possible, it is imperative that the amount of spendable funds available match the inflationary spiral so there are true increases in the gross amounts available.

Fred W. Whitehouse, M.D.
President

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October 10, 1978

Mr. Kurt Habel
Chief, Program Planning Branch
D.P.A., O.P.P.E.
Office of the Director
National Institutes of Health
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Bethesda, Maryland 20014

Dear Mr. Habel:

I am writing to provide some brief, additional comments for the record regarding the recent DHEW National Conference on Health Research Principles, held October 3-4 at the NIH campus. The APA gave oral testimony on the Draft Principles before each of the five panels, and submitted more extensive written comments to each of the Panels as well.

We are prompted to furnish these additonal comments because in the composition of the panels, in the questions and comments of panel members to APA staff giving testimony, and in the reports during the final plenary session of the conference, there was in our opinion inadequate attention given to the behavioral sciences, and insufficient recognition of their essential role in health research.

We achnowledge the progress that DHEW has made in recent years toward recognizing the behavioral sciences as essential and coequal partners in health research along with the biomedical and other sciences. Also, we were pleased that the Draft Principles made frequent mention of the biomedical and behavioral sciences together. However, old habits of thought and language die hard, and during the entire final plenary session hardly any of the panels mentioned the behavioral sciences along with the biomedical sciences, and the critical roles they both play in health research. We were concerned by this, because this oversight renders the behavioral sciences invisible, and may reflect a continuing opinion on the part of many in the health research community. Consequently, we felt it necessary to restate here the fact that the behavioral sciences are an integral part of an effective health research effort and we urge explicit recognition of this fact in the final panel reports and the composite final set of Principles.

Before proceeding further, let me say that APA strongly endorses the DHEW effort to develop multiyear, flexible plans for health research support, and as an initial step toward this goal, the development of a comprehensive set of principles to guide such planning efforts. The Department is especially to be commended for the open, consultative process of developing the Principles. As for the content of the Draft Principles themselves, APA has expressed its strong support for the thrust of the great majority of the Principles, and in several cases went beyond them to suggest plausible extensions and additional principles.

We were very pleased that some of the Panels advocated a broadened concept of health, which takes into account many dimensions of well-being, not merely the absence of disease. Conceiving of health in this broader fashion and conducting research on all relevant factors and approaches is the only truly effective way to improve the nation's health. It follows from this that all disciplines relevant to this broadened concept of health need to be taken seriously, encouraged, and fostered. Special care must continue to be taken to specify behavioral as well as biomedical research in the Principles and all discussions of them, not because behavioral research is more important, but rather because it is equally important, has been under-recognized by DHEW in previous years, and still is not routinely thought of by many traditional health researchers unless brought explicitly to their attention.

A serious commitment to the Principles also necessarily means providing an appropriate level of support to all revelant disciplines (in research, training, and physical resources), so they may realize their potential and in fact make the contributions that are needed and expected from them. We strongly agree with the Principles that the overall level of support for health research in general needs to be significantly increased, and that fundamental research should be protected. As part of this, support for the behavioral sciences must be signifcantly increased in both fundamental and applied research. We do not advocate increases in support for the behavioral sciences at the expense of support for other sciences. We have no interest in such a shortsighted policy which would divert needed fund from essential research in other areas. We do advocate significant increases in the overall health research budget, with a major share of those increases going for critical and long-neglected work in the behavioral sciences. We believe that a convincing case can be made for both of these proposals and offer our services to work with others toward that end.

Within the health research budget, we see the need for implementing three policy thrusts in order to make best use of the behavioral sciences in health research. First, support should be broad-based rather than narrowly targeted. Such a policy is inherently more stable, since it can better ensure steady scientific progress across a variety of fields. A diversity of approaches, each with adequate and stable support, is fundamental to consistent progress in health research. Second, there is need for greater support for interdisciplinary studies integrating the approaches of the biomedical and the behavioral sciences. Although each has its own unique contributions to make, in many cases greater progress (both scientific and practical) can be made by integrating approaches to a particular problem, rather than each being studied in isolation from the other. And third, we strongly support the Principles' call for continued reliance upon the peer review mechanism and for excellence as the primary criterion for research support. However, because behavioral science approaches are somewhat new for several funding agencies, special attention will have to be paid to ensure that reviewers are in fact qualified to review proposals with behavioral science components. In saying this, we are not asking for anything different from the standard policy in other health research areas; for example, NIH expects reviewers of research proposals on cancer to be extremely knowledgeable about cancer research. Our request is perfectly analogous.

It is important that all health researchers understand two crucial features of the behavioral sciences' relationship to health research. First, behavioral research is relevant not just to the psychological aspects of health, but also to the physical aspects, as well as to the complex intertwinings between the two. We need not dwell on this point, for recognition of this fact is reflected in recent increases in support for behavioral research from NIH.

Second is a point that was misunderstood by a few panel members at the conference: behavioral research in the area of health is not exclusively "applied research" but also fundamental research. The Unifying Concepts Panel made essentially this point in the final plenary session when they said that fundamental research does not refer to the size or number of objects being studied. In other words, fields other than the biomedical sciences are capable of performing fundamental health-related research in the true generic sense of that term: namely, the investigation of basic processes (whether biochemical, behavioral, social, or whatever) without regard for any immediate appplication of that knowledge. A few panelists had difficulty in conceiving that the behavioral sciences could do anything but applied research in the area of health. If the same sort of logic were to be used, it would be difficult for physicists to imagine that the biomedical sciences could be anything but applied research. This analogy is obviously extreme, but we use it to illustrate the faulty perspective from which such views are derived.

An example should clarify our point. Behavioral scientists, often working with other professionals, have done considerable research on the topic of patients' compliance with medical regimens prescribed by a physician. (The problem could be extended to non-medical health problems as well, but the medical example is perhaps clearest.) This is a major problem in the health care system, and the research is clearly of an applied nature. However, this research was not designed out of whole cloth on the spot. It has drawn on a tradition of solid fundamental research in the behavioral sciences including such areas as persuasion, information processing, social influence, and behavioral and attitudinal change. This example also illustrates a further point: without the fundamental research base to draw upon, the research on the applied problem of medical compliance would be considerably weaker and not readily generalizable beyond the immediate specific research settings used. This points up the necessity for fundamental as well as applied research in the behavioral sciences to be supported by DHEW.

I want to mention two broad areas of the greatest national importance where behavioral scientists are superbly qualified to contribute. These are prevention and evaluation research. We strongly support the call in the Principles for more balance in the support for research focused on prevention as contrasted with treatment, because we agree with the Principles that prevention is "more beneficial and less costly in the long run." A very large share of the issues in prevention, those dealing with health-promoting practices and avoidance of health-damaging practices, are essentially behavioral questions. As many prominent observers have noted, the major diseases responsible for the greatest numbers of deaths in recent years -- cancer, heart disease, and extensive cardiovascular disease (the so-called "diseases of affluence") -- are to a large extent dependent upon particular behaviors and lifestyles. Behavioral research can contribute much to preventive efforts in these areas. Similarly, accidents, injuries, and violence pose the primary threats (statistically speaking) to people under 30 years and the greatest cause of their death, disability, and malfunction. This suggests that preventive efforts such as environmental design and other behavioral change-inducing measures will be a major means for improving the health of young persons.* Again, behavioral research must obviously play a key role in such efforts.

The growing demand for professional and public accountability, together with escalating health care costs and the belated realization that many health services and technologies remain untested, are producing pressure for systematic evaluation of these areas. The current health policy system in the U.S. is inadequately cybernated, and urgently needs (1) a clearly elaborated set of goals specified in measurable terms so that progress toward those goals can be assessed; (2) basic evaluative information assessing progress toward those goals, especially with regard to the effectiveness and cost-effectiveness of various health programs and technologies; and (3) formal mechanisms for change incorporating the results of evaluation. We would agree with the thrust of Dr. Eisenberg's comments in reporting for the Health Regulations and Promotion Panel, when he stressed the cost-effectiveness of, and the returns to be gained from, systematic evaluation of health services and technologies. The United States spends in the neighborhood of $200 billion per year on health care. If careful evaluation studies resulted in only a 1 percent savings or reduction in these costs, it would nearly equal the entire DHEW health R&D budget. It is not unreasonable to expect that the returns would be considerably greater than 1 percent. If even a fraction of such savings could be diverted to urgently needed health research, the nation would be making a wise investment in its long-term health future.

The relevance of behavioral science to evaluation should be obvious. Psychologists and other behavioral scientists have been in the forefront in developing the methodologies of evaluation research, and can continue to make significant contributions to this area because of their sound training in science and research. We are enclosing a copy of principles for continuing evaluation and accountability controls for a national health insurance program, developed by an APA task force. Although developed in the context of an anticipated national health insurance program, it contains an excellent and persuasive argument for the role of evaluation in health services irrespective of whether a national health insurance program is established or not. These principles were intended as a public interest rather than parochial effort. However, I believe they illustrate rather well some basic orientations of behavioral scientists: (1) an emphasis on public accountability, in terms of both effectiveness and cost of health programs; (2) insistence upon empirical evidence to assess programs; and (3) an emphasis on systematic feedback for system design and adjustment.

In closing, I want to emphasize that the behavioral sciences have made, and can continue to make, major contributions to improving the nation's health. However, making effective use of the behavioral sciences will require attention to their unique characteristics and needs, as well as those shared with other disciplines. Again, we extend our willingness to work with interested groups and individuals on the issues discussed above, in what we believe is a common effort, namely, research which is ultimately dedicated to improving the nation's health.

Sincerely,

Charles A. Kiesler

Charles A. Kiesler, Ph.D.
Executive Officer

jb

Enclosures: 2
cc: Co-chairs of Conference Panels
Members of Unifying Concepts Panel

3902 Minden Road
Wheaton, MD 20906

13 October 1978

Mr. Kurt Habel
Chief, Program Planning Branch
D.P.A., O.P.P.E.
Office of the Director
National Institutes of Health
Building 1, Room 205
Bethesda, MD 20014

Dear Mr. Habel:

Conversation with the chairman of panel 5 (unifying concepts) National Conference on Health Research Principles, on 3 October 1978 is the basis for this correspondence. It was my understanding from the chairman that written testimony from members of the audience could be submitted to members of the panel within two weeks and such testimony would be considered for inclusion in the conference proceedings.

During the presentations by public witnesses before the panel (unifying concepts) members, there was for the most part, a general theme - more funding, and more concern for each of the respective organizations represented on the agenda. One area I would like to address, and which seems most appropriate for a panel of unifying concepts, is the vital importance of comparative medicine and animal models for research on human disease. As research on human subjects becomes more and more difficult and as medical schools devote substantially more of their resources to primalry health care education and research, the need for animal models of human disease grows increasingly acute. The development of a few comparative medicine programs has resulted in the discovery of many new animal models which now require exploitation. Support for such programs is urgently needed.

Quality assurance of laboratory animals needs continual upgrading. Defining genetic, infectious and nutritional disease parameters is imperative to assure quality animals for today's sophisticated research requirements.

It is hoped that with these brief comments the panel will consider favorably the requirements for research in comparative medicine.

Thank you for your consideration.

Sincerely,

Paul K. Hildebrandt

PAUL K. HILDEBRANDT, D.V.M.
Member, American Veterinary
Medical Assoc. Council on Research

National Conference on Health Research Principles
October, 1978

Comments on: Unifying Concepts

Submitted by: Leonie S. Watson, M.D.
Executive Director
National Doctors For Life
345-A Arguello Boulevard
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"Health research will be carried out in accordance with current social and ethical principles." (Attachment #2, page 20.) This statement is one of the unifying concepts proposed as a philosophic base for public funding of health research.

But can we rightfully allow the concept of "current" social and ethical principles to invalidate those principles which are basic and timeless? First among these basic principles are those which have assured the protection of every human subject. They affirm the inviolability of the rights of the individual even in face of broad societal concerns.

Are we now to endorse principles to suit current technological capabilities and perceived social needs without regard to these basic social and ethical principles?

We cannot, in justice, redefine human life to exclude human embryos and fetuses and then use these unborn human beings experimentally without regard to the guidelines for the protection of human subjects.

Nor can we rightfully redefine pregnancy to exclude the period before implantation and thereby remove protection from the pregnant woman and her child at the very beginning of pregnancy.

We cannot rightfully redefine human life according to any "current" standard based primarily on the quality of life if it excludes the lives of the severely ill, the aged, or the mentally retarded from the protection which we owe to every human being.

The pretext of 'broad societal concerns' does not justify a rejection of those fundamental principles which insure protection to all human beings, born and unborn.

As stated by Thomas Jefferson, "The care of human life and happiness, and not their destruction, is the first and only legitimate object of good government."

[illegible] Watson, M.D

GENERAL PUBLIC TESTIMONY

Cystic Fibrosis Foundation

Public Policy Office:
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NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES
OCTOBER 3-4, 1978

COMMENTS OF DORIS F. TULCIN, PRESIDENT
CYSTIC FIBROSIS FOUNDATION
6000 Executive Boulevard, Suite 508
Rockville, Maryland 20852

TO THE

PANEL ON FUNDAMENTAL RESEARCH
AND PANEL ON CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

I. The Cystic Fibrosis Foundation is a voluntary health agency concerned with the leading genetic killer of children and young adults in this country. We have recently worked with NIH in the preparation of a comprehensive report--"Cystic Fibrosis: State of the Art and Directions for Future Research Efforts"--which forced us to look at many of the questions this panel faces. We hope that our conclusions on research priorities, resources, and coordination will be helpful to you in your work.

After reviewing the "Draft DHEW Health Research Principles" prepared for this conference, the Cystic Fibrosis Foundation is concerned about the apparent division of research between "Fundamental Research" and "Clinical Applications." We believe that there is instead a research continuum including:

- research which is truly fundamental to our understanding of life processes;
- research which is fundamental to our understanding of a particular biological system or function;
- research which is necessary to our understanding of a particular health problem;
- research which investigates ways to alter a biological process; and
- research which attempts to implement a therapy at the patient care level.

A single project may involve more than one level, and the results of any work may yield unexpected spin-offs in unrelated areas. Yet each type of research is related in varying degrees of specificity to ultimate health needs.

GABRIEL KAPLAN
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For this reason, we urge you to address the research needs of all these levels in your panel discussions, and not limit yourself to the most basic biological research. If you were to do so, a large amount of important applied research would be "lost in the crack" between this panel and that on clinical applications.

II. HOW MUCH SHOULD THE RESEARCH PROGRAM BE "MANAGED"?

We would like to focus our comments on the issue of whether DHEW should actively direct the research program, or whether leadership should rest primarily in the scientific community. The Cystic Fibrosis Foundation strongly believes that funding decisions for biomedical research cannot depend solely on questions of scientific opportunity. We should not try to over-manage the research program, but we must have incentives to shift the weight of the effort towards higher priority areas. There is an incredible diversity of interesting questions which can be pursued in the health field, and we believe it would be irresponsible to fund research without adequate consideration of those areas where the most important problems remain.

There are two types of management relevant to this question. The first is the broad question of which general disease areas or scientific disciplines should get the most money. Because it fits more appropriately within the scope of the "Unifying Concepts" panel, we have discussed it in our submission to that group.

The other is how a research program should be conducted, once it is determined how much money it will have. We believe the Department should make more use of its store of high-quality studies and commission reports concerning different health problems. NIAMDD, for example, in recent years has received or will soon have reports concerning Cystic Fibrosis Diabetes, Arthritis, Kidney Disease, and Digestive Diseases. Each of these reports presents a comprehensive overview of the state of the art, the societal impact of the disease or health problem, and the most important research needs or research opportunities. We have attached several pages from the new Cystic Fibrosis Report showing how research priorities are set out.

We believe these reports should serve to shape the federal research program. We are pleased with the attention given to the Cystic Fibrosis report, and we have hopes that the important areas identified there will in fact receive priority attention. Formal encouragement of this process would help, and the research process will be aided by attacking problems in an orderly way.

In addition, comparing the reports would probably reveal certain questions that are common to a number of diseases. Such comparing should be done systematically so that important projects will be carried out without duplication or overlap.

III. HOW CAN THESE PRIORITY DETERMINATIONS BE TRANSLATED INTO POLICY, CONSISTENT WITH THE GOAL OF INVESTIGATOR FREEDOM?

We share the generally-accepted view that scientists pursuing projects they have chosen themselves are more likely to do good creative work than scientists under tight direction. Yet even within the independent peer-review process, NIH still has opportunities to influence the choice of research areas. Some of these methods are as follows:

- Workshops and conferences to bring together leading scientists who will discuss research priorities and opportunities among themselves, share new ideas, and perhaps become excited about new areas of research.

- Distribution of publications discussing the state of the art, especially those which address basic and clinical research needs and priorities.

- Where these methods do not produce an adequate response with respect to the most important areas, the Institute Directors should retain and exercise their power to adjust grant application priority scores within a limited range to shift the emphasis of research funding. This should be done with caution, but it can be especially important in a field where the research base necessary for substantial breakthroughs has not yet been developed.

- Willingness to pursue priority areas should be considered as one criterion in evaluating the quality of major grant applications, such as core grants, centers, and program project grants. When choosing between competing applicants for a limited amount of such funding, the record of the applicants in these priority areas should be given special weight.

- Finally, consideration should be given, as a last resort, to directing research through the contract process. This should not be done routinely, but where a major question remains as a stumbling block to an entire area of inquiry, that question must be answered through one means or another.

The Foundation believes that these methods are not inconsistent with the traditional peer-review grant process used to fund the bulk of biomedical research in this county. The Foundation strongly believes that a well-managed research program need not conflict with investigator freedom, and that the administration of federal research agencies should continue to address the needs of society at large.

TESTIMONY DIRECTED TO THE PANEL ON FUNDAMENTAL RESEARCH AND THE PANEL ON CLINICAL APPLICATIONS AND HEALTH SERVICES RESEARCH

National Society for Autistic Children

Dr. Edward R. Ritvo
Dr. B.J. Freeman

INTRODUCTION

On May 11 and 12 of this year, the National Society for Autistic Children participated in a Public Forum on formulation of a ten-year research strategy for the National Institute of Neurological and Communicative Disorders and Stroke at Chantilly, Virginia. The statement we made then is essentially the same one we are submitting for your consideration today. It was prepared by Dr. Robert Reichler, Chairman of our Professional Advisory Board.

Our belief that basic research, even when targeted on autism, will enhance our efforts to conquer many disorders, particularly those termed "developmental," is reflected in our statement. Specific areas for research (physiological and functional) are presented; specific suggestions follow. References throughout are to the Chantilly papers presented by the Epilepsy Foundation of America and the National Association for Retarded Citizens, which papers we hope will be made available to the Panels, either by NINCDS or by the organizations themselves.

Because research on autism is still in, not its infancy, but its fetal period, it cannot be separated into "Fundamental" and "Applied" with any validity. We have therefore chosen to present our statement to both relevant panels.

1- BIOCHEMISTRY: A number of studies have examined biochemical factors in autism, with special focus on the catecholamine neurotransmitters. Three major centers of biochemical studies have been Yale University, under Donald Cohen, UCLA under Edward Ritvo and Washington, D.C. under Mary Coleman and Don Boullin. While autistic children have frequently been found to be differentiated from other groups by biochemical measures, no consistant factor or pattern has yet emerged. There is consistantly a high variability within the autistic group. A major problem in such studies is the lack of objective diagnostic criteria and consequent inherent heterogeneity in populations studies and differences between populations in different studies.

2- ELECTROPHYSIOLOGY: Several investigators have explored EEG studies, evoked potentials and more recently, vestibular responses in autistic children. Itil has most persistently pursued electroencephalographic investigations, using a variety of techniques including spectral analysis. Small has conducted some studies focusing on the Contingent Negative Variation. Ornitz produced numerous studies primarily utilizing sensory evoked potentials and computer averaging techniques and, more recently, has been focusing on vestibular responses in autistic children. Tanguay has attempted to utilize a number of techniques, including evoked potentials to distinguish left-right cerebral differences in the autistic population.

3- ETIOLOGY: Several different approaches have emerged. Some studies, such as the Rubella studies by Chess and the investigation by Coleman of the association of autism with other disorders like coliac disease, have focused on autism as a sequelae or symptom of specific disease processes. Other investigators have explored the influence of viral infections, including slow viruses and pre-natal infections. Data is beginning to emerge from a large population study in North Carolina that suggest at least two distinct etiological clusters in the autistic population, one related to pregnancy risk factors and a second related to familial (genetic) factors. As in other areas of study, no clear consistant picture has yet developed.

4- OUTCOME: A significant number of outcome studies has been conducted in the United States and abroad, most especially in England. A fairly consistant picture of life-long disability for the majority of autistic persons emerges, with a significant part of the population remaining in the severely mentally retarded range and many with limited or absent speech.

4- TREATMENT: Scattered studies of treatment programs have been conducted. Most are relatively unsophisticated, anecdotal, or with few cases. The most consistant research has been by behavioral psychologists. The most regular funding supports structured behavioral interventions and educational programs. Psychopharmacological studies have been limited. The most consistant program has been conducted at New York University, initially by Barbara Fish and currently by Magda Cambell. While psychopharmacologic agents have demonstrated usefulness in gross management of autistic patients, they lack specificity, have serious side effects, and are variable in efficacy.

5- DIAGNOSIS: A number of different schema for the diagnosis of autistic children have been developed. While most overlap significantly, there remains significant disagreement as to how inclusive or specific the diagnosis should be. No objective diagnostic tests or criteria have yet been identified, although there is general agreement on the broader definition of the disorder (see attached "Official Definition of Autism" as approved by the NSAC Board and Professional Advisory Board). The lack of objective tests and criteria has hampered other research efforts. Neurobiological parameters which may be associated with a group of autistic children are obscured by the heterogeneity of the population. Attempts at earlier identification or elucidation of risk factors are rendered impractical.

RECOMMENDATIONS

Recommendations for research priorities are organized by topic areas which include a statement of general considerations, and specific generic areas of research. They reflect the current status of research on autism identified previously, and are referenced to the research priorities proposed by the Epilepsy Foundation of America and the National Association for Retarded Citizens.

General Considerations:

The value of categorical clinical designations such as mental retardation, epilepsy, cerebral palsy or autism for visibility and to focus advocacy for a particular group is undeniable and essential until the value of inclusion in another group designation can be shown to be more beneficial. Such categorical designations in the organization of research funding agencies assures at least a certain level of funding for a particular clinical disorder, and serves to foster and maintain involvement in the research enterprise. Despite these positive attributes, research funding organized largely or totally by clinical categories ignores certain essential facts and obfuscates the potential for the emergence of new perspectives. Research funding should recognize the fact that most of the developmentally disabled population is multi-handicapped, although often designated by major disability or predominant symptoms. A moderately retarded child with mild motor problems will be labeled retarded rather than cerebral palsied. For the autistic population, for instance, we know tnat 25 to 30 % will eventually develop seizures, that 70% are significantly mentally retarded, and that 25 to 30 % have significant motor problems. Because of the emphasis on categorical designations, children are most often designated as being autistic or retarded or cerebral palsied or epileptic rather than using the inclusive 'and'. From the research perspective, opportunities to identify linkages between these problems are diminished. From the treatment and service perspective, many of the needs of individual patients are disastrously ignored. Additionally, categories serve not only to designate who shall be included, but also force exclusion of other patients. Many children with developmental disabilities do not neatly fit in any of the major groups and are excluded, or when included are not optimally served by existing categories. Further, many of the problems of research and services for each of the developmentally disabled groups are similar or significantly overlap and they may at times be most effectively and efficiently served by the same program.

For these reasons, most research funding should not be confined to categorical clinical designations but should be organized by areas of study, techniques or function such as neurophysiology, behavior, etc.

Visibility for each clinical group can be maintained by several mechanisms. Some minimal level of funding specifically focused on each developmantal disability should be maintained. In addition, each developmental disability should be represented by a section in each appropriate agency or institute. These sections should not be primarily funding sections, but should encourage specific research through development of RFPs and contract mechanisms. These designated sections would also act as advocates for a specific group within their agency, function as coordinating units for agency and inter-agency activities and function as information coordinating resources.

EPIDEMIOLOGY OF DEVELOPMENTAL DISABILITIES

It is urgent to develop accurate data as to incidence, prevalence and identification of all developmental disabilities, including autism. Studies could identify potential antecedents of disorders as well as linkages between different categories or lead to a new classification system.

References: NARC - Field and Utilization Research, #3 and 4

C-690

EFA - Recommended action, #2 & 12, also possibly #3, 4, 9, 11, 19, 57

ETIOLOGY AND PREVENTION

Support pregnancy research as well as genetic, infectious disease, and socio-cultural studies.

Ref: NARC - Causes of Mental Retardation - #2, possibly #1
Preventing Mental Retardation - #1, 4, possibly #2
EFA - #9, 11, 15 & 19, possibly #10, 20, 22, 24, 25

DIAGNOSIS AND EARLY IDENTIFICATION

Support development of specific diagnostic techniques and development of classification systems. This will in part depend on developments in epidemiology and biomedical studies.

Ref: NARC - Causes of Mental Retardation - #2-C
Behavioral Research #1
Mentally Retarded in Society #3
EFA - #3, 4, 57 - possibly 29, 30, 31

BIOMEDICAL FACTORS

Neurophysiological bases of developmental disabilities with focus on neurotransmission, functional organization in the CNS, hormonal functions and effects and immune mechanisms.

Ref: NARC - Causes of Mental Retardation - #2
EFA - #17, 21, 27, 34 - possibly 5 & 10

PSYCHOLOGICAL FACTORS

Support studies in psychological function such as learning, memory, cognition, speech, motivation, and social and behavioral problems.

Ref: NARC - Behavioral Research - #1
EFA - #28, possibly 29, 30 and 31

TREATMENT

a) Pharmacology:

Development of new drugs and evaluation of efficacy of drugs, hormones and other chemical agents. Should include studies of pharmacokinetics and long term effects of pharmacologic agents.

Ref: NARC - #2
EFA - #35, 37, 38 & 45

b) Behavioral and Educational:

Research on optimal techniques for management and education of developmental disabilities. Research should range from management to self management, etc. Need development of evaluation programs which identify individual strengths, deficits and needs. Research must include evaluation of treatment and education programs. Good basis could be the study and evaluation of already established programs.

Ref: NARC - Intervention and Amelioration - #1 and 3
EFA - #54 and 55, possibly #29, 30, 31 and 50

c) Preparation for and Integration in Community Living:

Studies of skill development, vocational training and community placement. Studies should include development and evaluation of rehabilitation programs, the design of the environment and alternate living arrangements. Evaluation of service delivery systems, and cost-benefit / cost-effectiveness should be included.

Ref: NARC - Intervention and Amelioration - #5
Mentally Retarded In Society - #1 and 2
Field and Utilization - #1
EFA - #52, possibly 50

DISSEMINATION

Review, Integration and Dissemination of newly developed knowledge is essential for stimulation of new research and implementation of findings into service programs. Use of Abstract Retrieval System for all developmental disabilities should be considered. Dissemination methods could include sponsorship of conferences.

Ref: NARC - Additional Considerations - #1
EFA - #42, possibly 59, 60, 61, 8

TRAINING

In order to familiarize more related professionals with problems of the developmentally disabled, training funds should be provided to support programs specifically designed for developmental disabilities training. With increasing numbers of the developmentally disabled population remaining in the community, it is imperative to educate those professionals, especially physicians, who are being trained primarily for the care of adults, to the needs of the developmentally disabled.

STRATEGY

Those priorities of NARC and EFA were selected for support which most effectively serve the broad developmentally disabled population. Designations of appropriate agencies with responsibility for each program component is easily developed, as in the EFA proposal. Most important is the development of interagency coordination and collaboration. Often research is so poorly funded in any one agency that it does not allow for strong support of even essential areas. With improved mechanisms for interagency collaboration, funding for all areas could be significantly improved. Also, it is imperative that even relatively narrowly conceptualized categorical programs allow the appropriate inclusion of other groups.

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December 11, 1978

Dr. Donald S. Fredrickson
Director
National Institutes of Health
9000 Rockville Pike
Bethesda, Maryland 20014

Dear Doctor Fredrickson:

The American Academy of Pediatrics was represented, but made no formal presentation at the National Conference on Health Research Principles, October 3-4, 1978. It is our understanding that there was no statement presented at the conference, advocating research for children.

We are writing you, as the Conference Chairman, to request that the attached position paper be added as an addendum to the conference report. It represents the position of the American Academy of Pediatrics and of the American Pediatric Society, on the research needs of children and youth. Portions of the paper were contained in a letter from David Goldring, M.D., in a letter of October 20, 1978 to Secretary Califano.

We appreciate your consideration of this request.

Sincerely,

Robert G. Frazier, M.D.
Executive Director

RGF:tz
Enc:

POLICY STATEMENT ON PEDIATRIC RESEARCH

The greatest benefit, in terms of both cost and quality of life, will derive from research that guarantees to parents the birth of healthy and wanted children and to children the opportunity to achieve healthy and productive adulthood. To ignore the health research needs of children, women of reproductive age, and families denies the opportunity to eliminate a group of medical and social problems that impose the heaviest burden on our society.

These critical areas of research received scant attention from the conferees on health research principles who focussed almost exclusively on categorical and disease-oriented programs. This omission is of grave consequence for health research planning and for society. We urge that fundamental research attendant to problems of reproduction, human development, and behavior be emphasized and identified in reports of all the Panels on Health Research Principles.

There is increasing evidence that diseases and disabilities manifested in adulthood may have origin in childhood. Moreover, debilitating patterns of behavior that compromise adult health-smoking, alcoholism, and poor nutrition--may become established early in life.

Research in reproductive biology and behaviorial science would help assure that each child is born at a time when his or her parents are prepared and able to offer every opportunity for growth, learning, and personal development.

Studies that focus on human growth and development constitute a critical base for preventive medicine. Health care applied during pregnancy, at birth, and in childhood can prevent a multitude of problems of immediate and long-range consequence including prematurity, infectious disease, mental retardation, and birth defects.

Habits and patterns of life-style that compromise adult health are increasingly attributed to learned and acquired behavior in childhood. Research in the behavioral and social sciences uniquely provides knowledge that can promote health and prevent disease through studies on parenting, learning, and personal development.

Specifically, we urge that the following be considered in the formulation of principles:

- Fundamental research activities in reproductive and developmental biology must be maintained and strengthened.

- Basic and applied research in the behavioral and social sciences must receive increased support.

- * Long-term investment in non-categorical research, as represented by reproductive and developmental biology and the behavioral and social sciences, must not suffer at the expense of focussed, disease-oriented programs.
- * The prevention of disease and disability, before it is manifest, provides the greatest benefit to cost ratio.
- * The development of clinical applications to prevent disease is as important as the development of methods to cure and treat disease.
- * Children are our nation's most vital and precious resource. Their right to flourish from birth through maturity must be assured through research that seeks to eliminate problems of pregnancy and birth, diseases of childhood, and disorders that compromise learning, and personal and social development.
- * The ability to contain and achieve fertility safely and effectively is of paramount importance to the well-being of families and children.

We are hopeful that the allocation of health research resources will be guided by appropriate concern for the future of our children and the well-being of families, and we are prepared to offer whatever assistance is required to achieve this vital objective.

November 1978

American Association of Neuropathologists, Inc.

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October 16, 1978

Dr. Donald S. Fredrickson
Director, National Institutes of Health
Bethesda, Maryland 20014

Re: Health Research Principals

Dear Dr. Fredrickson:

The American Association of Neuropathologists is the only national organization that has as its purpose the advancement of the science and practice of neuropathology. Our membership of almost 500 includes nearly every neuropathologist in the United States and Canada and many neuroscientists doing fundamental research in neuropathology. Our Association supports the Health Research Principles described in the DHEW draft. It also wishes to emphasize the importance of:

1) Increased funding for fundamental research. Neurological diseases cause severe disabilities and death, and are a major national health problem. They deserve a bigger share of the national research budget. Future budgets should allow for inflation and rising administrative costs, both of which have greatly reduced what can be purchased by investigators for research. Good neuropathology research programs usually are interdisciplinary and can flourish in departments of pathology, neurology, or neurosurgery. Because of their expertise in evaluating morphological changes in diseased and experimentally altered nervous tissue, physician-trained neuropathologists are principal investigators in many fundamental research programs that investigate basic mechanisms of human neurological diseases.

2) More support for clinical application of neuropathological research advances. Twenty years ago, fundamental research established the importance of electron microscopy, histochemistry and other techniques in neuropathology. New neurological diseases have been discovered and the causes of others identified. Much of this technology still is not available in many medical centers even though it may be required to make the correct diagnosis. In the specialized field of neuropathology, clinical application of research techniques deserves more support. If provided it will produce better patient care and accelerate research progress.

3) Expanding research capability in neuropathology. Neuropathologists receive at least 4 years of post-doctoral training. Additional research training is essential to provide skills needed to run an imaginative independent research program that can compete successfully for available funds. Recent cutbacks in training and research funds have reduced opportunities in a field where the need for well qualified investigators is increasing. Therefore, support for training research neuropathologists and for both junior and career investigators must be increased to provide an adequate future research capability in neuropathology.

The American Association of Neuropathologists appreciates your interest and would like to continue participating in the process of establishing health goals and an appropriate budget to achieve them.

Sincerely,

Henry deF. Webster

Henry deF. Webster, M.D.
President

National Institutes of Health
Building 36, Room 4D04
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THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

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October 20, 1978

Honorable Joseph A. Califano, Jr.
Secretary
Department of Health, Education and
Welfare
Washington, D.C. 20201

Dear Secretary Califano:

The American College of Obstetricians and Gynecologists is pleased to continue its participation in the effort to determine national health research principles. We regret that our recommendations follow the October 3-4 Conference, but the Department of Health, Education and Welfare request for comments did not reach our office until October 10. However, we are asking that this response be included in the record of the National Conference on Health Research Principles.

The College is an association of more than 20,000 physicians specializing in the health care of women and has identified four priority areas for research pertinent to our field of practice: adolescent pregnancy, low birth weight, premature onset of labor, and family planning. Recognizing the valid and significant contributions of other groups participating in this effort, we confine our comments and recommendations to our selected priority concerns. Since the problem of adolescent pregnancy is exemplary of these priorities, it will serve to illustrate our suggested approach to defining research principles.

The Administration and Congress have acknowledged the seriousness of the adolescent pregnancy problem in our country. Legislation in the form of the Adolescent Health, Services, and Pregnancy Prevention and Care Act of 1978 has moved from Congress to the President's desk and, when enacted, will provide the framework for HEW's coordination of the disparate regional and local services for this population in need. One disappointing factor in the recently-approved legislation is that only $500,000 of the $55,000,000 appropriated will be directed to research on the various elements of adolescent pregnancy.

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We feel a professional and ethical obligation to recommend the inclusion of increased funding for research in this critical area as a part of the National Institutes of Health future operating budget. Consistent with the title of this legislation, prevention must be given the proper emphasis to avoid, where possible, the difficult disposition of a pregnancy in which all options are likely to be traumatic and costly. If adequate *fundamental research* of the medical and social issues is conducted, our society will benefit as pregnancy truly becomes a matter of choice.

A component of the increased research budget should be a focus on the *clinical applications* of the research findings designed to ascertain diversified and alternative methods of providing reproductive health services to women in the relevant age group. Specifically, and typical of our suggested emphasis on preventive research, it is recommended that behavioral research studies which investigate the motivation and peer climate of adolescents with respect to pregnancy and provision of health services should be a part of a clinical applications research budget.

Additionally, research funds should be directed toward improving existing educational programs for the prevention of unwanted pregnancies and to promote the health consciousness of the pregnant adolescent through new programs. The *health promotion* research needs related to adolescent pregnancy illustrate the one anomalous feature of the structure HEW is using to state and examine research principles and policy. We feel that the five principles, as stated in one or two sentences each by the Department, are valid, basic and noncontroversial, except that the statement regarding *health promotion and regulation* reflects a confusion of methods and functions.

In relation to adolescent pregnancy and many other dimensions of personal health, there are whole areas of health promotion (and the research which supports it) that cannot and/or should not result in regulatory activities. Furthermore, in many cases regulatory agencies and their procedures are ill-suited to carrying out health promotion research or activities. The American temperament generally rebels at regulation by government of its style of living "for your own good."

Regulation of products, of environmental hazards, and of working conditions is necessary. Research should be fostered by the Department to establish the risk/benefit relationships involved, and the results applied in a judicious manner in the public interest. However, government oversteps its bounds and frequently defeats its own purpose when it attempts health education and promotion as a subset of regulatory activities. Although a common thread of preventive purpose may run through regulation and health promotion, we urge the Department to distinguish cleanly between them in all its endeavors.

Having discussed the application of the suggested principles that address segments of the health research continuum in terms of research on adolescent pregnancy, let us mention briefly the other areas we feel should be accorded research priorities.

The College strongly supports the inclusion of research on low birth weight and premature onset of labor in the Institutes' proposed five-year research budget and subsequent research strategy. We feel that by funding research which is focused on the critically important stages of pregnancy and early infancy and searching to understand the developing biological mechanisms, much can be learned to prevent not only deformities at birth but also childhood and adult diseases and conditions that may have antecedents determined during the prenatal period.

Research with respect to fertility and infertility is essential in the research budget. Again, the elements of volition, motivation and regulation must be kept discrete and in balance. Research must lead to the freedom to decide when and if to begin a family and the number and timing of those births should be an individual's choice. With this control exercised by the individual in a safe and responsible manner, she can control the quality of her own life and that of her offspring -- an especially critical choice for the adolescent.

We must continue our research efforts to assure the availability of a variety of safe methods of contraception, appropriate for all age groups, and designed to meet a diversity of needs. Furthermore, we need to address the concerns of the infertile couple and acknowledge their need for research and resolution of the problem of infertility that faces a large number of Americans.

In conclusion, the American College of Obstetricians and Gynecologists urges the adoption of research principles which reflect a genuine concern for improving the totality of health care for Americans, based upon a preventive, promotional approach, rather than solely curative, responsive methods. Health promotion through well-designed research programs may moderate the growth in health care costs by reducing reliance on remedial procedures, needed because we lack the knowledge for earlier intervention, and by eliminating other wasteful methods. Increasing competence and knowledge in all aspects of human reproduction is the best investment we can make for the health of future generations. We are convinced of the soundness of this approach to research policy and urge the Department of Health, Education and Welfare to consider these comments accordingly.

If we may provide further information or contribute to your decision-making process at any time, we encourage you to call on us, particularly since the one or two Conference panel members knowledgeable in reproductive health were confined by the format of the hearing to a limited scope of participation.

Sincerely yours,

Warren H. Pearse, M.D

Warren H. Pearse, M.D., FACOG
Executive Director

WHP/bc

**American
Liver
Foundation**

A national voluntary health
agency concerned with the
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and cure of liver diseases

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The Gail I. Zuckerman Foundation
Riverdale, New York

November 10, 1978

The Honorable Joseph A. Califano, Jr.
Secretary of Health, Education and Welfare
Department of Health, Education and Welfare
Washington, D.C.

Dear Secretary Califano:

The American Liver Foundation and the American Association for the Study of Liver Diseases are deeply interested in the plan to develop a five year health research program and budget. We wish to express our views regarding research strategy as applied to liver disease, and potential criteria for selecting research targets.

The American Liver Foundation is a non-profit, tax-exempt, voluntary health organization which was established in 1976 to prevent premature death and disability from liver disease. Its members consist of interested laymen and physicians. The latter are members of the American Association for the Study of Liver Diseases which is over 25 years old and represents academicians and practitioners with major interest in liver disease.

We find the suggestions which were distributed at the National Conference on Health Research Principles to be meritorious. The challenge is to translate them into assessments of health research objectives and to build a framework about which these objectives will hopefully be met.

The spectrum of research and health needs regarding liver diseases in the United States is considerable. The categorical area encompasses viral, drug and chemical-related hepatitis; cirrhosis of the liver due to many etiologies; acquired and inheritable liver diseases in children; gallstones; cancer of the liver, and the essential role of the liver in metabolism, nutrition and survival. In many of these areas, research advances have dramatically changed our understanding of the problem and, in some cases, have provided unexpected means of diagnosis and treatment. The best illustrations are the discovery of specific hepatitis viruses and new possibilities regarding vaccines,development of effective medical treatment for cholesterol gallstones, and identification of drugs and chemicals which cause liver injury and cancer. In each of these areas, contributions from basic sciences have led to new concepts of disease and subsequent application to diagnosis and management; the basic science contribution was one of serendipity rather than planning! Neither the discovery of Hepatitis B virus nor the role of chenodeoxycholate in treatment of cholesterol gallstones was programmed. They resulted from broad levels of investigative inquiry which often had little to do with the objective for which the studies were first designed.

We are concerned that in the effort to plan missions for federal research health agencies and to determine their specific priorities, individual investigator-stimulated research studies, which are not immediately identified as related to major health issues, will have restricted funding. This is an old argument and worry; however, there are increasing pressures to justify, program and direct research activities into areas likely to produce results. In our opinion, goals and applications of methodology are desirable; however, they cannot substitute for basic inquiry into cellular processes which underly most of our ignorance of disease.

We are greatly concerned by the increasing weakening of bridges which span basic science and pathophysiology of disease. The spectacular advances made by biological scientists in the past decade have created knowledge, technology and theoretical concepts which, at an increasing rate, are not being applied to the study of human diseases. Academicians interested in applying basic science advances to the study of liver disease have decreased in number and support. At the moment, there is a remarkable shortage of such individuals in the American academic scene. This depletion of talented young investigators is not unique for liver disease and is broadly represented in many areas of medicine. Reduced research funds, inflation, financial attractions of clinical practice, and, fundamentally, a lack of stability in funding mechanisms contribute to this ever-increasing gap. We believe that in liver disease and other areas of medicine, this gap deprives the American public of rapid development of new techniques for diagnosis, treatment and prevention of liver disease. Attention must be paid to stabilizing research support for young investigators and to encourage them into the academic scene. We hope that efforts to create a five-year plan do not freeze budget levels and distribution of funds, and increase competition to the extent that young investigators are no longer attracted into the interface between basic science and clinical medicine. A study group connected with the recent National Commission on Digestive Disease presented evidence indicating that less than 60% of current academic positions in gastroenterology-liver disease are filled and that, within the next five years, the figure will drop more dramatically. In the national effort to provide best results in health research, we sincerely urge that the primary investigator-sponsored research grant be given highest priority, and that substantial attention be paid to the need for bridging the gap between basic biological sciences and the understanding of disease.

Because public money provides the major support for bio-medical research, it is essential that the public be made more aware of the nature of the scientific process. In particular, we are concerned that politicization of the scientific process has, in the past, made promises to the public which has then become embittered on recognition that stated goals were not obtained. It is essential that the public be educated better about the nature of the scientific process and its limitations in predictability, particularly as a short term investment. A more open approach is necessary for the public to understand that solution of specific health problems requires a knowledge base in research opportunity which cannot, in itself, be predicted. Serendipity in medicine is the rule and not the exception. Few members of the lay public understand this.

In much of medicine, therapy is pragmatic. Clinical trials to evaluate diagnostic tests and therapeutic procedures are currently in vogue. These trials are expensive and divert large sums of money from investigator-oriented research activities. We hope that the desire to provide short-term accomplishments, as reflected by clinical trials, will not weaken the overall structure of research support and complicate acquisition of fundamental knowledge. Because pharmaceutical and other corporations usually benefit directly from clinical trials, one might consider creation of a co-operative program between government and industry to sponsor clinical trials.

In the field of liver diseases, we lack considerable epidemiologic information. We have no idea as to the nature and mechanism of many diseases as they occur in society as distinct from in hospitalized patients. Encouragement of talented young men and women to enter epidemiology and develop the sophistication and skills for its proper use is a major challenge.

Development of a full-scale five-year health research budget could, in principle, stabilize federal funding, resist disease-oriented group pressures, and help organize health research efforts of the country. We are concerned that the plan does not damage the flexibility which has existed in the system to date, make the health research budget rigid and, in the long run, make it more difficult for young investigators to bridge the gap to which we have referred.

The American Liver Foundation congratulates you and your colleagues on encouraging a careful assessment of the federal support of health research. We are happy to contribute our interest and expertise in any manner.

Respectfully submitted,

Irwin M. Arias, M.D.
Chairman, Scientific Advisory Committee
American Liver Foundation
Councillor, American Association for the Study of Liver Diseases
Director, Liver Research Center, Albert Einstein College of Medicine
Bronx, New York

IMA:ell

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October 20, 1978

The Honorable Joseph A. Califano, Jr.
Secretary of the Department of
Health, Education, and Welfare
Washington, D.C. 20201

Dear Mr. Secretary:

The membership of the American Pediatric Society wholeheartedly endorses your dedication to our country's health research enterprise and, especially, your attention to the problems of women and children. The needs of this population, so often neglected in the determination of research priorities, received important emphasis with your support of the National Institute of Child Health and Human Development.

The deliberations of the National Conference on Health Research Principles were followed carefully by our Society's representatives, Dr. Robert L. Brent, Professor of Pediatrics and Radiology of the Jefferson Medical College, and Dr. Joseph Dancis, Professor of Pediatrics, New York University.

Their report prompts me to convey the Society's grave concern that the health needs of children and families were neglected in the considerations on health research principles.

It is the Society's conviction that the greatest benefit, in terms of both cost and quality of life, will derive from research that guarantees to parents the birth of healthy and wanted children and to children the opportunity to achieve healthy and productive adulthood. To ignore the health research needs of children, women of reproductive age, and families denies the opportunity to eliminate a group of medical and social problems that impose the heaviest burden on our society.

These critical areas of research received scant attention from the conferees on health research principles who focussed almost exclusively on categorical and disease-oriented programs. This omission is of grave consequence for health research planning and for society. We urge that fundamental research attendant to problems of reproduction, human development, and behavior be emphasized and identified in reports of all the Panels on Health Research Principles.

There is increasing evidence that diseases and disabilities manifested in adulthood may have origin in childhood. Moreover, debilitating patterns of behavior that compromise adult health--smoking, alcoholism, and poor nutrition--may become established early in life.

Research in reproductive biology and behaviorial science would help assure that each child is born at a time when his or her parents are prepared and able to offer every opportunity for growth, learning, and personal development.

Studies that focus on human growth and development constitute a critical base for preventive medicine. Health care applied during pregnancy, at birth, and in childhood can prevent a multitude of problems of immediate and long-range consequence including prematurity, infectious disease, mental retardation, and birth defects.

Habits and patterns of life-style that compromise adult health are increasingly attributed to learned and acquired behavior in childhood. Research in the behavioral and social sciences uniquely provides knowledge that can promote health and prevent disease through studies on parenting, learning, and personal development.

Specifically, we urge that the following be considered in the formulation of principles:

- Fundamental research activities in reproductive and developmental biology must be maintained and strengthened.

- Basic and applied research in the behavioral and social sciences must receive increased support.

- Long-term investment in non-categorical research, as represented by reproductive and developmental biology and the behavioral and social sciences, must not suffer at the expense of focussed, disease-oriented programs.

- The prevention of disease and disability, before it is manifest, provides the greatest benefit to cost ratio.

- The development of clinical applications to prevent disease is as important as the development of methods to cure and treat disease.

- Children are our nation's most vital and precious resource. Their right to flourish from birth through maturity must be assured through research that seeks to eliminate problems of pregnancy and birth, diseases of childhood, and disorders that compromise learning, and personal and social development.

- The ability to contain and achieve fertility safely and effectively is of paramount importance to the well-being of families and children.

The American Pediatric Society is hopeful that the allocation of health research resources will be guided by appropriate concern for the future of our children and the well-being of families, and we are prepared to offer whatever assistance is required to achieve this vital objective.

Sincerely yours,

David Goldring

David Goldring, M.D.

STATEMENT OF THE ASSOCIATION OF AMERICAN VETERINARY MEDICAL COLLEGES FOR INCLUSION AS PART OF THE PROCEEDINGS OF THE NATIONAL CONFERENCE ON HEALTH RESEARCH PRINCIPLES

W. M. Decker, D.V.M.
Washington Representative

Directed to the Panel on Research Capability, the Panel on Fundamental Research, and the Panel on Unifying Concepts

In the preliminary reports at the closing plenary session of the National Conference on Health Research Principles, several needs were identified which are of interest to and can be met by the veterinary medical profession.

In particular the summary of Dr. William Danforth for the panel on Research Capability spoke to improvements necessary in developing human, animal, and physical resources.

In the recent past, training grants to produce young scientists, have been curtailed. At the same time, fewer physicians have been entering fundamental research careers. The veterinary medical profession is also suffering from a lack of veterinarians academically educated and trained for careers in research and teaching. We would strongly encourage the recommendations of the Committee to broaden the support for training programs of pre- and post-doctoral candidates, to increase the levels of these awards in order to remain competitive, and to provide more encouragement for young investigators when they finish their training. Special consideration should be given to direct more effort to encourage minorities to participate in these activities. The veterinary medical profession stands ready and willing to continue to commit resources toward comparative medicine, the protection and advancement of human health, and research fundamental to medicine as a whole. Encouragement to develop scientific manpower capabilities can and will lead to more rapid developments in research.

Of special interest to the veterinary medical profession is the request by this Committee for a greater effort to find animal models of human disease. The colleges of veterinary medicine and the departments of veterinary science are a unique and untapped source for the identification and development of animal models. Each university veterinary school clinic processes thousands of animals each year with essentially no conscious or coordinated effort expended to compare the animal diseases identified with counterpart diseases of man. The departments of veterinary science as well as the colleges either operate diagnostic laboratories for their respective states or are closely affiliated with them. We now rely on serendipidous events to uncover potential new models of human diseases in animals.

We propose that special attention be given in terms of a funded program which would make proper use of this potentially valuable but now wasted resource. Funds sufficient to provide faculty, training stipends, staff, and facilities should be clearly identified in order that the process of discovery, characterization and propagation of animal disease models can be accomplished as quickly as possible in times when the ability to do human research is becoming progressively restricted.

As is the case with other research institutes, the problem of maintaining adequate research facilities and equipment has been hampered by the reluctance of granting agencies to provide monies for equipment, renovation and new construction. Continuation of these policies will lead to an impressive deficit in capabilities which will then only be solved by heroic measures in time of some great emergency. We agree with the Committee on Health Regulation that the premise that resources for research are limited is a political one if, in fact, less than 1% of the health care budget is allocated in this area.

Finally we agree with the Committees on Fundamental Research and Unifying Concepts that stable research funding must be established in order to accomplish the goals envisioned by citizens to promote an adequate level of health and health care for all. To accomplish needed stability certain concepts must be acceptable:

1) Some fundamental research should be supported merely for its own sake.

2) Most basic knowledge is not a direct product of directed research.

3) Investigator initiated research should prevail.

4) Discretionary funds must exist to fund emergency needs.

5) Fundamental research has no relationship with the size of the organism studied - molecular and populations both qualify.

6) Efforts should be supported to resist major funding allocations to "disease of the month" promotion.

7) While peer review is still the best method of review, it must change to allow the funding of new areas and innovative ideas.

8) Funding should be for 5 years at a time.

Association of
Teachers of
Preventive
Medicine

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November 7, 1978

Julius B. Richmond, M.D.
Assistant Secretary for Health
U.S. Department of Health, Education
and Welfare
Humphrey Building
Washington, D.C. 20201

Dear Dr. Richmond:

On October 12, 1978, Charles B. Arnold, M.D., MPH wrote to you expressing his pleasure that the National Conference on Health Research Principles was held, and his concern with the relative lack of attention given to behavioral research as compared with that given to biological research. On behalf of the Association of Teachers of Preventive Medicine, I would like to support both Dr. Arnold's pleasure and his concern.

For most of the top ten killer diseases and conditions of the population of the United States, a great deal is already known concerning important associated risk factors: cigarette smoking, alcohol consumption, dietary imbalances, exercise habits, automobile driving and leisure activity patterns, and stress, all of which contribute to the make-up of the American "life-style." If ways can be found to positively affect behavioral change for health among Americans, consistent with the traditions of democracy, a great deal can be done to improve life-expectance and the quality of life in the later years without finding biological "causes and cures."

Because of the apparent multi-factorial causation of many of the modern killers and chronic diseases, it may not be possible in any case of find "causes and cures" for all of them. Therefore, behavioral research in preventive medicine should receive at least equal priority with biological research, as our national effort in health sciences research proceeds.

To Dr. Arnold's offer of assistance to you in developing programs and policies in these areas, I am pleased to add my own and that of my organization.

Sincerely,

F. Marian Bishop

F. Marian Bishop, Ph.D., MSPH
President

FMB/cs

cc: Dr. Charles Arnold, American College of Preventive Medicine
Dr. Thomas Morgan, Association of American Medical Colleges

COALITION FOR HEALTH FUNDING STATEMENT ON STRATEGY FOR HEALTH RESEARCH

DR. JOHN F. SHERMAN, PRESIDENT

Introduction

The membership of the Coalition for Health Funding appreciates the opportunity of adding its comments and observations to those of other organizations as part of the development by the Department of Health, Education and Welfare of a multi-year strategy for health research.

The Coalition, which was created in 1970, was established by representatives of non-profit organizations concerned with the appropriation of an adequate level of Federal funds for health programs. The entire effort of the organization is directed to the attainment of that objective. It presently consists of approximately 55 member organizations. The Coalition is vitally interested in efforts by the Department to place the funding of these programs on the most rational basis possible.

The following observations or recommendations are offered for consideration by those charged with the actual development of the DHEW health research strategy:

1. We vigorously support the concept of quality of programs as being the most important determinant in the effectiveness of the numerous efforts carried out by the Department to improve the health and well-being of our fellow citizens. All too frequently in the areas of health professional education, in the delivery of health services, and in biomedical and behavioral research, there are pressures especially through the political process, to reach decisions or to fund activities using a primary criterion other than the quality of the proposed effort or of the individuals who would be involved.

2. In order to best assure a selection process in which quality will be emphasized and maintained a system of peer review for the assessment of research proposals should be employed. Adequate resources should be provided so that the system will function efficiently and effectively. Proper safeguards

to avoid conflicts of interests should also be featured.

3. A vigorous, diversified program of research on the fundamentals associated with human health and disease should be highlighted as sine qua non in the overall program of health research. Only through constant replenishment and expansion of the knowledge base, which is possible only by that approach, can the expectations of the public be fulfilled.

4. There should be recognized the importance of each of the individual elements of the continuum of research and the relationships and feedback requirements with that continuum:

fundamental --> <--- applied --> <--- developmental --> <---

demonstration --> <--- broad application

5. In any master long-range strategy, provision must be made for a reasonable degree of flexibility so as to accommodate the dynamic character of research and the unpredictable nature of its pace and directions. All too frequently and with the best of intentions, strategies are predicated on inadequate data or determinants which may change radically during a period, such as five years.

6. The need for constant infusion of new scientists into the manpower pool should be given a high priority in the overall strategy. This is necessary to be certain that new ideas are introduced and replacement of non-productive researchers occurs. This is not to say that the Federal government should fund all research training, but it should have the responsibility for monitoring the adequacy of that pool in both its qualitative and quantitative dimensions. If either dimension is threatened, the federal government should be prepared to support the training effort promptly and adequately.

7. Essential resources other than human such as laboratories, equipment and libraries, must be periodically assessed so that their quality, quantity, distribution, and condition is such as to facilitate rather than to inhibit the research effort. As for the intellectual resources, the Federal government should assume the vital surveillance and assurance role.

8. Reasonable stability in Federal purpose and funding would greatly facilitate maximum effectiveness and efficiency in health research programs. The long-term nature of most research activities is incompatible with the much shorter periods of authorizing legislation and appropriations. The problem is one which the Congress in particular should address.

9. The dissemination of new knowledge in prompt, accurate and comprehensive manner to both health practitioners as well as researchers is of great importance to the success of the nation's health research enterprise. Updated libraries, refereed journals and new technologies in information handling offer major opportunities for improvements in this area.

10. A reasonable degree of confidentiality for selected parts of the health research enterprise is a requisite for the most productive research effort and therefore the assurance of the public good. Although wherever possible the business of government should be conducted in open session, certain elements which are of marked significance to scientists as individuals should be viewed from another perspective. The life blood of a successful scientist is his ideas and the opportunity to carry them out. Therefore, documents describing those ideas, such as research grant applications, deserve the protection of confidentiality, at least until after the proposal has been funded. A corollary of a specific nature is the need to avoid inadvertent or premature disclosure of potentially patentable ideas. Another element

deserving a measure of confidentiality is the review of applications for scientific merit by panels of scientific experts. Unless their deliberations can be conducted in an atmosphere which fosters the most candid and searching examination of proposals, the public interest is ill served.

While not all-inclusive, the Coalition advocates these considerations as highly important for inclusion in any multi-year strategy for health research. We are convinced, as well, that the adoption and successful implementation of a well developed strategy will require the provision of Federal financial assistance in adequate measure and with due regard for increments over time in the level of funding. All evidence supports our contention that the public is willing to back such increments as reasonable and acceptable. In our view development of the knowledge base is the one certain means to control other health costs.

Richard J. Wurtman, M.D.
Professor of Endocrinology
and Metabolism

Massachusetts Institute of Technology
Laboratory of Neuroendocrine Regulation

I believe that there is a broad realm of important research to be done in what one might term "nutritional physiology". This centers on determining which metabolic processes in the body *normally* are influenced by variations in the availability of substrates derived from the diet, and of discovering what of significance happens in the body when these reaction rates change as the result of eating. This set of problems differs from those that traditionally have constituted the main thrust of nutritional research, nutritional *pathophysiology* (e.g., what happens in *mal*nutrition, when the body receives inadequate amounts of vitamins, proteins, or other nutrients).

It is now well known that the amounts of nutrients that would be needed to saturate many enzymes and transport systems (including, for example, those which synthesize several brain neurotransmitters) are much greater than those actually present in the tissues. Hence *normal* post-prandial increases (or decreases) in the plasma concentrations of these nutrients are able to cause corresponding increases (or decreases) in the rates at which they are acted on by enzymes, or transported into tissues. One suspects that a considerable part of the public's conception that it "feels better" or worse, or more or less happy depressed, sleepy, alert, and so forth, after eating particular foods may indeed have a definable molecular basis related to changes in the tissue levels of a key nutrient. One also anticipates that the of which reactions in the body are nutrient-dependent will suggest new ways of using food constituents to treat *non*-nutritional diseases (e.g., lecithin for tardive dyskinesia; tryptophan for myoclonus), and may also help to explain why numerous systemic diseases affect mood, "tiredness", appetite, alertness, and seemingly-unrelated brain functions.

The main problem, it seems to me, in developing this area is the apparent lack within the federal government of a constituency that identifies nutritional physiology as important, and commits itself to supporting research and training in it and in related fields. Sometimes it seems that agencies tend to equate the domain of proper nutritional research with mal-nutrition; - or to consign it to gastroenterology-hematology; - or to conclude that the only real "National Nutrition Problem" is the distribution of nutrients to people who can't afford them or don't choose to consume them; - or to dismiss as idealogy or commercial propaganda the claim that what one eats can be important, even when eaten by a non-malnourished person. The number of first-rate scientists and physicians working in this field is small (partly for the reasons outlined above), - but its potential for rapidly contributing to the health of Americans is enormous. Moreover, any such program that educates physicians and their patients about the range of effects that nutrients normally can have must ultimately contribute to the solution of a growing national medical problem: The schism between those largely lay people on the one hand who purvey (and accept) food myths - which cause people to waste very large sums of money, and often to follow bad advice for their medical problems - and those physicians and scientists on the other who, knowing very little about nutritional physiology, categorically deny that there may be something worthwhile in it for them to know.

I am Richard J. Glassock, M. D., Chairman of the Scientific Advisory Board of the National Kidney Foundation, and Professor of Medicine at the UCLA School of Medicine. I am appearing on behalf of the National Kidney Foundation, the largest voluntary health organization dedicated to the needs of patients with Kidney and Urologic Diseases. Kidney and Urologic Disease constitutes a major health problem in the United States. Such diseases result in hospitalization of approximately 300 patients per 100,000 population per year and account for approximately 3,000 outpatient visits per 100,000 population per year. The total dollar cost of such care is unknown but could approximate 4 billion dollars per year. Furthermore, the enactment of Public Law 92-603 with its provision for coverage of expenses for dialysis and kidney transplantation has resulted in an additional cost to the Federal Government for treating end stage kidney disease of approximately one billion dollars in 1977. These expenses provide care for approximately 34,000 patients on dialysis and for 4,500 patients receiving kidney transplantation. In contrast, total Federal support for research in Kidney and Urologic Disease was approximately 53 million dollars in fiscal year 1976. Thus, Federal research expenditures constitute only about 1% of the total cost of health care in Kidney and Urologic Disease. Furthermore, at the present time only one out of every three approved research grant applications in the field of kidney disease are funded by the National Institutes of Health. A large number of these approved research grants were of the highest scientific merit and many of them addressed areas of research identified as high priority.

In this context, a report of the Coordinating Committee on a Study of Research Needs in Nephrology and Urology was recently issued. This study was supported by a contract from the Department of Health, Education and Welfare (NIAMDD) and was generated by a large number of distinguished scientists and investigators. It addressed the overall question of long term research needs in the general field of kidney and urologic disease. The following major disease areas were identified as of the highest priority and opportunity for fundamental biomedical research which would significantly contribute to alleviating the problems of kidney and urologic diseases:

1. Glomerulonephritis: This family of diseases accounts for approximately one-half of all kidney disease leading to progressive and permanent impairment of renal function. There is every indication that current research efforts will in the foreseeable future lead to the development of powerful tools to prevent and treat this group of kidney diseases.

2. Hypertension: Elevated blood pressure (hypertension) continues to be an important cause of end stage kidney disease. Currently available treatment methods not only control hypertension but prevent progression of diseases of the kidney, heart and other parts of the blood vessel system. A complete understanding of the causation of the most common type of hypertension is not yet available.

3. Congenital Diseases: Congenital diseases of the kidney and urinary tract are responsible for a considerable amount of morbidity and disability in children and young adults. We still have only the most rudimentary insight into the abnormalities that are characterized as congenital or hereditary diseases of the kidney and urinary tract.

4. Kidney Stones: The occurrence of stones in the kidney and urinary tract results in many thousands of days of disability and hospitalization each year. The tools are available to probe the disturbances of biochemistry leading to stone formation and knowledge in this area is presently available which could lead to the ultimate prevention of most stone disease. The funding of Specialized Centers of Research for Urolithiasis during the last Congress is a most appropriate and promising initiative.

5. Infections: Infections of the kidney and urinary tract produce an enormous amount of illness and disability in Americans of all ages. Although we have a large armamentarium of drugs to control and prevent destruction of kidney tissue by infection, there is a crucial requirement for ongoing investigative efforts designed to elucidate the basic causes of kidney and urinary tract infections.

6. Prostate Gland: Diseases of the prostate gland include prostatitis, a poorly understood but important clinical problem in young and middle-aged men. Current research initiatives may ultimately give us a better understanding of the causation and prevention of this widespread problem.

Thus, the long term needs and priorities in kidney and urinary tract diseases have been clearly identified and characterized. The scope and magnitude of the problem is well recognized. Present funding of biomedical research in kidney and urologic disease is inadequate by any standards.

The National Kidney Foundation applauds the purpose of this Conference and endorses wholeheartedly its goals. We believe that the plan emanating from this Conference should be flexible and involve the biomedical research community in its ongoing review. Federal funds allocated for research should bear some relationship to the total societal costs of disease. Personnel training and manpower development should be recognized as vital to the continued excellence of biomedical research. Young investigators should be encouraged to enter the field of biomedical research. Investigator initiated research proposals should be given priority over targeted, mission oriented research. Replenishment of obsolete equipment in established research facilities should be a major goal of any plan.

In summary, kidney and urologic disease represents a health problem of major proportions both in terms of human suffering and dollar cost. Extensive study has identified major long term research needs. A plan for the resolution of these problems incorporating the concepts mentioned would be of great value to society. The National Kidney Foundation stands ready to assist the Federal establishment in achieving these goals.

Thank you for the opportunity to have appeared before this conference.

Richard J. Glassock, M. D.

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PANEL 1

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PANEL 5

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